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FEDERAL POLICIES AND THE MEDICAL DEVICES INDUSTRY

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Foreword

In recent decades, both the range of medical devices and the industry that manufactures them have greatly expanded. At the same time, there has been growing Federal involvement in the U.S. health care system. The Medicare and Medicaid programs established in the 1960s have increased the market for medical technologies and have greatly influenced patterns of payment and use. The Federal Government instituted a premarketing approval process for medical devices in 1976. Other activities, such as funding research and development, regulating the providers of medical devices, and providing medical care for veterans, have involved the Government in the development and purchase of medical devices.

Since the late 1970s, congressional committees have been interested in the effects of such Federal policies on the companies that manufacture medical devices. In early 1982, this interest resulted in a request from the Senate Labor and Human Resources Committee to the Office of Technology Assessment (OTA) for an assessment of Federal policies and their effect on the medical devices industry. The Senate Veterans' Affairs Committee endorsed the request and expressed particular interest in the activities of the Veterans Administration regarding device development and procurement.

In preparing this report, OTA staff drew upon the expertise of members of the advisory panel for the study, members of the OTA Health Program Advisory Committee, and experts in health policy, industry, research and development, economics, health administration, and medicine. Drafts of the final report were reviewed by the advisory panel, chaired by Dr. Richard R. Nelson; OTA's Health Program Advisory Committee, chaired by Dr. Sidney S. Lee; and other individuals and groups with expertise in the area. We are grateful for their assistance. Key OTA staff involved in the preparation of the document were Jane E. Sisk, Cynthia P. King, John C. Langenbrunner, Katherine E. Locke, Lawrence H. Miike, and Judith L. Wagner.

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1.
Introduction and Summary

No one has yet managed to measure the state of technical knowledge, much less the rate of change of technological knowledge.

—*M. Blaug*

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1.

Introduction and Summary

Medical devices are a striking feature of U.S. medical care. The past generation has seen the development of a tremendous range of devices whose use has improved or prolonged people's lives and revolutionized medical practice.

Some medical devices have enabled people with what would otherwise be debilitating conditions to improve their functioning. Artificial hip joints, for example, have enabled elderly people with crippling disabilities to walk and live independently. Other devices have extended people's lives. The Scribner shunt has permitted long-term hemodialysis for end-stage renal disease, and the cardiac pacemaker has controlled certain arrhythmias of the heart.

Still other devices have drastically altered medical diagnosis and treatment. Starting with automated blood chemistry analyzers, clinical laboratories have shifted from manual to mechanized procedures, with consequent improvements in the speed, accuracy, and per-unit cost of tests. New imaging devices, such as the computed tomography (CT) scanner, ultrasound, and mammography, often obviate the use of more dangerous, painful, and costly procedures, such as exploratory surgery. Innovations in needles, sutures, and microscopes have greatly improved cataract surgery.

The industry that manufactures medical devices in the United States has grown in tandem with these developments. From less than $1 billion in 1958, industry sales grew to more than $17 billion in 1983. Even after adjustment for inflation, industry sales increased sixfold during that period. About 3,500 companies now employ more than 200,000 people, compared with about 65,000 employees in 1958.

These changes in the medical devices industry have occurred during an era of growing Federal involvement in the U.S. health care system. The Medicare and Medicaid programs, which were enacted in 1965, have greatly increased health insurance coverage, expanded the market for medical devices, and influenced their development and use. Between 1960 and 1982, primarily because of the growth in Federal programs, the share of medical expenditures paid by third parties rose from 45 to almost 70 percent.

The kind of health insurance coverage that has evolved in this country has insulated the buyers and users of medical technologies—mainly physicians, hospitals, and patients—from the cost of many medical services, especially those provided in hospitals. The purpose of health insurance programs such as Medicare is to permit people to obtain needed medical care without risking financial ruin. But there is discretion involved in the use of medical technology, and for many devices, insurance coverage has reduced the importance of cost as one of the few factors that motivate discretion. Some devices, especially those associated with prevention and rehabilitation, are less likely to be covered by insurance than others and may be relatively underused.

The Medical Device Amendments of 1976 significantly expanded the Food and Drug Administration's (FDA) authority to regulate medical devices for safety and efficacy. This and other Federal activities, such as supporting research and development (R&D), regulating the purchase and use of devices by medical providers, and delivering medical care to veterans, have substantially involved the Government in the market for medical devices.

Congressional committees have been interested since the late 1970s in the effect of Federal policies on the companies that manufacture medical devices. There has been particular concern that the newly established Federal regulatory process for devices might be harming technological innovation and small companies. In early 1982, this interest resulted in a request from the Senate Labor and Human Resources Committee to the Office of Technology Assessment (OTA) for an assessment of Federal policies and their effect on the medical devices industry. The Senate Committee on Veterans' Affairs, in endorsing that request, raised issues related to the Veterans Administration (VA) and its role in technology development and procurement. This report has been prepared in response to those requests.

SCOPE OF THE STUDY

Medical devices span a vast array of supplies and equipment, from frequently purchased items with low unit cost, such as bandages and syringes, to infrequently purchased items with high unit costs, such as clinical laboratory and imaging equipment. The definition of a medical device used for this study is taken from the 1976 Medical Device Amendments (Public Law 94-295) to the Federal Food, Drug, and Cosmetic Act. Thus, the term medical device refers to any instrument, apparatus, or similar or related article that is intended to prevent, diagnose, mitigate, or treat disease or to affect the structure or function of the body. This definition excludes drugs, which achieve their effects through chemical action within or on the body. Medical devices are thus one class of medical technology as defined by OTA.[1]

A wide range of Federal policies helps to frame the social, political, and economic context of the market for medical devices. This report concentrates on Federal policies that have the greatest leverage over the kinds of medical devices produced and the price at which they are sold: policies pertaining to payment for health care, support for R&D, regulation of the safety and efficacy of medical devices by FDA, regulation of medical providers, and development and procurement of devices by the VA. Policies that extend to the entire economy, such as those regarding taxation, financial capital, patents, and export control, are excluded from detailed analysis. Although these broader policies may affect medical devices, any options for changing them would require an analysis that reached well beyond the confines of the medical devices industry or this report.

As background to an analysis of Federal policies regarding the medical devices industry, it is important to note that medical care differs from many other products that are bought and sold. Patients often do not have the expertise to evaluate medical technologies and therefore tend to rely on medical professionals for guidance concerning which medical services and devices to use. Even medical professionals, however, often lack the expertise to assess sophisticated devices, a fact that underlies the regulatory process established by the 1976 Medical Device Amendments.

Photo credit: E. I. du Pont de Nemours & Co.

Medical devices encompass a broad range of products, including not only sophisticated, expensive equipment such as computed tomography (CT) scanners, but relatively simple and inexpensive items, such as bandages, syringes, and stethoscopes.

Governmental programs such as Medicare reflect the social concern that people be able to obtain some minimum level of care, regardless of their ability to pay. Benefits from the use of some medical devices and other technologies, especially those to prevent and treat infectious disease, include increases in overall levels of health and productivity and are thus greater for society than for the individuals who use the technologies. Governmental public health programs to immunize young children and to test their vision reflect the societal importance attached to the use of such medical technologies.

The remainder of this chapter summarizes the chapters in the body of the report: characteristics of the medical devices industry, payment policies for health care and devices, FDA regulation of devices, R&D policies related to devices, regulation of providers, and VA policies regarding devices. Appendix A describes the method of conducting the study, and appendix B acknowledges the valuable assistance of several individuals. Appendixes C through I contain material on topics that relate to but are broader than medical devices: innovative activity, patent policy, tax policy, consensus standards in international trade, and foreign regulation of international trade. In addition to this main report, six case studies of specific devices, a technical memorandum on the policies of the VA, and a compilation of inventors' vignettes are being published in connection with this assessment.

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[1] OTA has defined medical technology to include drugs, devices, medical and surgical procedures, and the organizational and supportive systems within which medical care is provided.

SUMMARY

In recent years, a number of problems have been perceived in the cost, efficiency, quality, and innovation of medical devices, all of which relate in some way to Federal health care policies. Since 1978, U.S. expenditures for medical care have been rising at an annual rate of 13 to 16 percent, much faster than the rate of growth in the U.S. gross national product. Although studies have not documented the precise role of medical technology in escalating medical care costs,[2] the adoption of new, sophisticated medical devices, such as CT scanners, and overuse of existing devices, such as automated clinical laboratory analyzers, have often been implicated as contributing factors.

In addition to concerns about the growth or level of health care expenditures, there is concern about whether the benefits gained in improved health or reduced worry have been worth the costs. This concern stems from the prevalence of health insurance, which has changed the balance between costs and benefits for people who buy and use medical technologies. Health insurance, especially Federal programs, was originally intended to make basic medical care accessible to people who might otherwise not be able to pay for it. But recent concerns about costs have muted such distributional issues. And some cost-effective interventions that are not well covered by insurance, especially in preventive and rehabilitative care, are probably underused.

Issues more directly related to medical devices pertain to the quality of products marketed and used, including their safety and efficacy, and to continued innovation in the field. Concerns raised in the early 1970s about fraudulent and hazardous devices culminated in the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act. The regulatory process for devices under this act, in turn, has led to concerns about whether such regulation will impede innovation, which has long been a hallmark of the medical devices field, and whether the degree of consumer protection gained is worth the costs.

The Federal policies most prominent and probably most influential in the medical devices field have been those pertaining to health insurance programs, chiefly Medicare and Medicaid, and regulation of marketing. As discussed in this report, however, policies pertaining to R&D, regulation of providers, and veterans have had a substantial role as well.

Federal funding of R&D has been a longstanding Federal activity, mainly within the purview of the National Institutes of Health (NIH). Federal R&D in medical devices, as in other fields, has been intended to stimulate worthwhile innovations that private developers might not otherwise undertake.

Federal and State regulation of providers who purchase and use devices was an early response to rising medical expenditures. Such regulation has had two goals in addition to cost containment: ensuring that people receive care of acceptable quality and ensuring that the distribution of facilities is equitable.

The Federal Government has sought for many years to ensure that veterans have access to medical care, including devices. In carrying out its mandate, the VA has been involved in the full range of activities from R&D through purchase of devices. Because of the many VA medical centers and individual veterans who rely on the agency for devices, the VA has substantial leverage in the market for many devices.

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[2] See OTA's report *Medical Technology and Costs of the Medicare Program* (342) for estimates of technology's aggregate contribution to health, hospital, and Medicare costs.

The Federal policies just mentioned are frequently inconsistent, as one would expect of programs that have different, often conflicting, goals: ensuring access to medical care for veterans, elderly and poor people; containing the cost of that care; ensuring acceptable quality of care; protecting public health and safety; stimulating worthwhile innovations; and minimizing the adverse effects of regulation on manufacturers. This report and the remainder of this summary chapter describe and analyze these policies with respect to their effect on the medical devices industry.

A thorough grounding in current and recent Federal policies is particularly important for assessing policy changes that are contemplated or under way. In the area of payment for medical care, tremendous changes are under way that may affect devices. Medicare and some private third-party payers are beginning to pay hospitals a fixed amount set in advance for each case.[3] The adoption of this type of prospective payment method for hospitals may substantially change the market for medical devices and may have implications for the international trade position of U.S. manufacturers. In the process of implementing the new payment system, Medicare is developing policies that will affect medical devices, such as how to pay for capital expenditures and how to ensure use of care that conforms to an acceptable level of quality.

Another important policy area is FDA regulation of medical devices and the balance between protecting the public's health and minimizing the regulatory burden on manufacturers. Major portions of the Medical Device Amendments have yet to be implemented, and implementation of some may not be feasible.

Payment Policies for Health Care and Medical Devices

In general, health insurance has stimulated the medical devices field by providing a secure and growing market for the products used in medical care. The effects of insurance on the market for specific devices have varied, depending on the coverage of the devices as benefits, the methods of payment for covered devices, and the financial relationship between the payer and provider of care.

In recent decades, the sales of devices whose use has been well covered by insurance, such as X-ray and electromedical equipment and surgical equipment and supplies, have grown much more rapidly than sales of devices such as dental supplies and ophthalmic goods, for which patients pay a much greater share of the cost. Medicare and most other health insurance programs cover inpatient hospital care more fully than care provided in other locations, such as physicians' offices and ambulatory laboratories. Some kinds of medical care and their associated devices, such as preventive technologies, eyeglasses, and hearing aids, are excluded from coverage or covered to a very limited extent.

Most methods of third-party payment for medical care used in the past have encouraged the adoption and use of medical devices because providers have received more payment with greater use of technology. Physicians and clinical laboratories have been paid by Medicare, some Medicaid, and many Blue Cross/Blue Shield plans for the charges they have billed, subject to limits set according to the fee levels prevailing in the area. Besides stimulating use of technology, these charge-based payment methods have encouraged price increases because insurers have used recently billed charges to set new levels of payment.

Hospitals have traditionally been paid according to the charges they have billed or the costs they have incurred. Traditional hospital payment methods have encouraged the adoption and use of medical technologies and have discouraged price or cost containment.

Recently, however, Medicare and some States have begun to pay hospitals prospectively (i.e., with rates set in advance of the time when they apply). In October 1983, Medicare started to pay hospitals a fixed amount per admission that varies across 470 different diagnosis related groups (DRGs). The amount now covers only inpatient operating costs; capital, outpatient, and teaching expenses are continuing to be paid on a cost basis for the time being.

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[3] See OTA's technical memorandum *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology* (341).

Medicare's DRG payment system provides incentives for hospitals to become much more cost conscious in their adoption and use of medical devices and other resources. Whereas hospital payment methods in the past have encouraged providers and manufacturers to emphasize nonprice factors, DRG payment encourages them to give more prominence to price considerations. **Especially favored by DRG hospital payment are devices that lower the cost of a hospital stay by reducing the costs of services provided or by shortening the length of stay.** Hospitals are likely to increase group purchasing, standardize their purchases, and require competitive bidding for equipment and supplies.

How DRG rates are changed in future years to reflect changes in prices and technology will affect incentives to develop and use new devices. As payment incentives change, many U.S. device manufacturers will face an adjustment in their product development and marketing strategies, from stressing quality to placing more emphasis on price. However, such a change promises to make U.S. devices more competitive internationally if U.S. companies can more effectively challenge foreign ones on the basis of price as well as technology.

The exclusion of capital expenses from the DRG hospital payment rate fosters the adoption of durable equipment and facilities relative to more labor-intensive services, with inadequate regard for the total benefits and costs of each. Congress has stated its intention of including capital in the prospective rate by 1986. Another problem is that because Medicare's DRG payment system applies only to operating costs for inpatient care, it encourages the adoption and use of devices and other resources in settings such as home health care and hospital outpatient facilities, where DRG payment is not in effect. In some cases, such as surgery for cataract removal and placement of an intraocular lens, it is possible that the movement away from inpatient care may reduce cost and benefit the patient. But DRG payment as now established fosters changes in that direction with inadequate regard for the effects on total costs of care or benefits to patients.

Policy options can address these problems in specific areas of medical care and device use. **One approach would be to develop payment methods with financial incentives that are more neutral with respect to physicians' decisions to use devices and that encourage physicians to select the least costly settings of use.** Currently, for example, physicians have financial incentives to order and perform clinical laboratory tests in their offices

Photo credit: E. I. du Pont de Nemours & Co.

Automated clinical chemistry analyzers, first developed in the 1950s, improve the speed and accuracy and lower the per-unit costs of laboratory tests on blood samples. Their use, however, has been implicated as a source of rising medical expenditures.

and to use procedures associated with new devices for which high fees may be set. Congress could require Medicare to experiment with payment methods for laboratory and physician services that are mindful of incentives regarding the use of different technologies and locations of care.

Congress could also encourage Medicare to experiment with alternatives to reasonable charge reimbursement of durable medical equipment and to unify payment policies regarding parenteral or enteral nutrition therapy for patients receiving and not receiving home health services. Congress might also consider including capital in Medicare's DRG hospital payment rates, so that hospitals consider the cost of equipment and facilities when making decisions about resources to purchase and use.

The above options that address problems in specific areas of medical care and device use would continue payment methods with basic shortcomings. These methods encourage the use of medical technologies, including devices, because providers are paid more for using more services, and encourage technology use to shift to less restricted, more lucrative locations. The resulting pattern of use of devices and other technologies is unlikely to reflect their relative costs and benefits. **A different policy approach would be to move Medicare in the direction begun with DRG payment. Congress could encourage Medicare to set overall limits on the amount to be paid for care and to permit providers and patients to determine the use of specific devices and other technologies within that limit.** Such methods of per-case or per-person payment could be applied to physician services, all hospital care, or the full range of medical care.

Regulation of Medical Devices by the Food and Drug Administration

FDA regulation of medical devices was intended to protect consumers' health and safety by ensuring that marketed products are effective and safe. The Medical Device Amendments of 1976 provided more effective methods for dealing with fraudulent devices and attempted to anticipate and minimize the potential risks associated with increasingly sophisticated devices. Congress also intended that the regulation impede innovation in the field as little as possible.

The Medical Device Amendments provided for regulation according to the degree of potential risk posed by a device. Devices that had been marketed before 1976 were to be assigned to one of three classes: Class I, encompassing devices for which general controls such as good manufacturing practices were deemed adequate to ensure safety and efficacy; Class II, an intermediate category, for devices for which general controls were deemed insufficient to ensure safety and efficacy and for which performance standards could be developed; and Class III, for devices that support life, prevent health impairment, or present an unreasonable risk of illness or injury and require FDA approval before marketing.

With limited resources, FDA has set priorities in implementing the 1976 Medical Device Amendments. By early 1984, while the majority of the medical specialty classification panels set up by FDA had completed classification of the device types[4] assigned to them, the others had only proposed classifications. Twenty-seven percent of the device types are in Class I; 64 percent are in Class II; and 8 percent are in Class III.

To obtain FDA's market approval, all Class III devices are required to show evidence of safety and effectiveness. However, preamendments Class III devices were given a 30-month grace period before FDA could require such evidence, and FDA may extend that period. Furthermore, until evidence is required for their preamendments equivalents, postamendments devices found "substantially equivalent" to Class III preamendments devices may be marketed without additional proof of safety and effectiveness.

FDA could have expedited the classification of potentially high-risk Class III device types *within each* medical specialty category, thereby starting the grace period after which evaluation of Class

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[4] A device type may include all products of a particular type (e.g., cardiac pacemakers) or grouping of devices that are similar (e.g., obstetrics-gynecology specialized manual instruments).

III preamendments devices of these types could begin. Instead, FDA has completed classifications of device types in the medical specialty categories in which most of the device-associated deaths and injuries have been and continue to be reported—e.g., cardiovascular (pacemakers, heart valves) and obstetrics-gynecology (intrauterine devices (IUDs)). Furthermore, in September 1983, FDA expressed its intention of reviewing evidence of safety and effectiveness for 13 preamendments Class III device types that it considers of highest priority. Documentation of safety and effectiveness of products of these types will be needed for their continued marketing.

Another of FDA's priorities has been to implement the premarket approval process for postamendments Class III devices. Guidelines for the procedures by which investigational Class III devices may be tested and evidence gathered had been completed by FDA by 1980.

FDA's premarket approval process has been applied to only a small fraction of the devices marketed after 1976. Postamendments devices that are found substantially equivalent to a device already on the market are automatically classified and regulated like their preamendments equivalent. By the end of fiscal year 1981, only about 300 of the 17,000 products submitted for clearance to FDA after 1976 had been found not substantially equivalent. Although products that are not substantially equivalent are automatically placed in Class III, the manufacturer can petition FDA for reclassification, and some manufacturers have done this.

No performance standards have yet been developed for Class II devices. In practice, therefore, Class II devices have been regulated like Class I devices. In mid-1983, FDA identified 11 priority Class II device types for which it was starting to develop the first performance standards. There is a consensus among industry and consumers that although an intermediate class of devices is advisable, it is impractical for FDA to formulate performance standards for the more than 1,000 device types now designated as Class II.

Other examples of how FDA has set priorities in implementing the Medical Device Amendments can be cited. In 1980, for example, FDA exempted 30 Class I device types in the General Hospital and Personal Use category from the requirement that their manufacturers notify FDA before marketing them. The manufacturers of these device types, which include medical absorbent fibers and specimen containers not represented to be sterile, continue to be subject to FDA registration and surveillance for conformity with good manufacturing practices regarding manufacture, packing, and storage.

Substantial negative effects of the 1976 Medical Device Amendments on the medical devices industry have not been documented to date. Perhaps this result is not surprising, because major sections of the law have not been fully implemented. Patents on medical devices, one indicator of innovative activity, have shown the same trends as before the law, with a higher rate of awards continuing for more sophisticated devices. Manufacturers have reported increases in R&D, sales, and new devices introduced since the Medical Device Amendments, and national data bear out these reports. One-third of the manufacturers responding to a national survey in 1981 had entered the industry after the amendments, and 80 percent were optimistic about business in the field during the next decade. Surprisingly, however, almost half of the survey respondents stated that Federal regulation had been a major problem for them.

The regulations have been more burdensome to small manufacturers than to large ones; smaller manufacturers reported higher regulatory costs per employee than larger ones. Small establishments are particularly important in the medical devices field: about 70 percent of all establishments have fewer than 20 employees, and these small establishments have historically accounted for substantial innovation. The law expressed particular concern about small manufacturers by requiring that FDA establish an office to provide them information. Although large manufacturers in the 1981 survey were much more likely to consider producing a Class III device, it is noteworthy that this situation existed before the amendments as well. Thus, regulation may intensify this pattern but did not originate it.

The amendments have posed the greatest problem for small manufacturers of contact lenses. Because some contact lenses were regulated as drugs before 1976, the newer types of lenses were automatically placed into Class III. Over the years, small manufacturers have found it difficult to enter the market because of the expense of gathering clinical evidence on safety and effectiveness. The public policy goals at odds in this case are preserving the confidentiality of information from manufacturers who have already received approval to market their devices versus increasing the availability of products, with price competition as one result.

Available information does not permit an assessment of consumer protection under the Medical Device Amendments. **Although the primary goal of the amendments is to protect public health and safety, there exists no systematic information on the extent to which problems of safety and effectiveness are occurring.** Without such information, one cannot assess the effect of FDA's choice of priorities in implementing the law. Information from FDA's present voluntary system of reporting device hazards and from product recalls is inadequate, because it does not indicate the magnitude or frequency of device-related problems. Voluntary reports and recalls for high risks have mostly involved implantable devices, often with electrical problems, and cardiovascular devices. Since 1980, FDA has proposed several approaches to mandatory reporting by manufacturers and expects to issue a revised proposal in 1984.

Congress has several options to improve FDA's regulation of medical devices. Insofar as an overall regulatory approach is concerned, Congress could continue the basic framework and intent of the 1976 law and adjust specific provisions to reflect judgments on the appropriate balance between methods of ensuring safety and effectiveness and the costs of these methods. An alternative strategy would be to revise the law to reflect the status quo with regard to FDA's implementation of the law. A third approach would be to revise the law to exclude certain device types from regulation on the basis of their potential risk.

To address the issue of what evidence of safety and effectiveness should be required for preamendments Class III devices, Congress could continue FDA's emphasis on high-priority device types, limit requirements for evidence of safety and effectiveness to device types identified as problems, or encourage FDA to accept a greater range of evidence. To address the issue of when the evidence should be required, Congress could allow FDA to continue its interpretation that the end of the grace period is the *earliest* date that FDA can require evidence, or could establish the end of the grace period as the date when FDA *must* call for evidence. Other congressional options pertain to possible revisions in the substantial equivalence method of market entry for postamendments devices.

There is widespread agreement that performance standards cannot be developed in a timely fashion for all of the devices types that have been placed in Class II. Congress could authorize FDA to use other methods, such as voluntary standards or designation of prescription devices, to regulate Class II devices. Other options include legislating an additional category of Class II devices with different requirements or reclassifying most existing Class II device types into other classes.

Information on risks associated with medical devices is crucial to assessing the 1976 law and its effectiveness in consumer protection. Congress could require FDA to develop better systems for monitoring and providing information on device risks or encourage FDA to selectively apply postmarketing controls to regulate Class II devices.

To help manufacturers, especially small ones, through the regulatory process, Congress could encourage FDA to use publicly available information to down-classify Class III devices as soon as possible. FDA might also act as a broker between small firms with promising devices and clinical investigations capable of gathering data to support premarket approval for Class III devices.

R&D Policies Related to Medical Devices

The present level of private R&D for medical devices appears to be generally adequate. If industrial R&D in medical devices responds to market opportunities, as it does in other fields, the greater demand for most medical devices because of health insurance would argue that medical devices R&D has been adequately stimulated.

From 1974 to 1980, R&D grew at an average annual rate of about 16 percent in medical devices companies, as compared with a rate of about 12 percent in industry as a whole. In 1980, company-sponsored R&D as a percentage of sales was greater in medical devices than in industry as a whole (2.9 percent compared with 1.6 percent). The percentage of company-sponsored R&D devoted to basic research differed only slightly in medical devices firms and in industry as a whole (3.7 percent compared with 4.1 percent).

Basic research has long been recognized as subject to underfunding by private companies. As research becomes more targeted to development of a commercializable device, however, the case for governmental involvement declines. Federal support has been lower for R&D conducted in medical devices companies than for industrial R&D as a whole. In 1980, the Federal Government funded less than 3 percent of the R&D conducted by medical devices firms, compared with 29 percent of that conducted by industry as a whole.

Under a new Federal program, the Small Business Innovation Research (SBIR) program, NIH and other Federal agencies with sizable R&D budgets must set aside a small percentage for R&D awards to small businesses. Although NIH funds for the SBIR program may come at least partly from funds that would otherwise have gone to basic research and nonprofit institutions, the redistributional implications of the program are not yet clear. The program's solicitation and selection methods merit attention as the funds devoted to this effort increase.

The Orphan Drug Act of 1983 (Public Law 97-414) charges the Federal Government to identify and promote orphan products, including both drugs and medical devices. Devices that are very valuable to potential users, especially in relation to their cost, and that are so costly that it would be unreasonable or inequitable to expect potential users to pay a price sufficient to cover production costs, are by definition worthy of support. However, it is difficult to distinguish between such orphan devices and devices that lack a sufficient market because they are not worthwhile.

Neither the Orphan Drug Act nor regulations have provided sound criteria for identifying orphan devices. By spreading payment across many people, third-party payment may render previous orphan devices and services affordable. Medicare coverage of dialysis for end-stage renal disease is an example. Expensive devices are usually covered by health insurance, and many of those not covered, including preventive and rehabilitative devices, may have a large enough market to permit sale at a sufficiently low price. But the problem of orphan devices may grow as third parties develop increasingly restrictive payment policies.

The Orphan Drug Act makes available to orphan drugs certain benefits (e.g., grants and contracts for clinical testing) that are not available to devices. It appears premature to extend the benefits of the Orphan Drug Act to devices until criteria are developed to distinguish orphan devices from those that are not worth their costs. However, an option would be for Congress to mandate that the Department of Health and Human Services develop criteria and methods for identifying orphan devices.

Regulation of the Providers of Medical Devices

Federal regulation of the providers of medical devices applies mainly to facilities, such as hospitals, but affects physicians indirectly. Such regulation has been undertaken to promote good quality medical care, to control rising costs by evaluating technology adoption and use, and to ensure access to care, including medical devices.

As a condition of receiving funds from Medicare, hospitals have periodically had to review the medical necessity of admissions, extended stays, and professional services. The reviews performed by Professional Standards Review Organizations (PSROs) focused more on reducing overutilization of inpatient care and on containing costs than on reducing underuse or improving overall quality of care. The emphasis of PSRO review was consistent with the incentives of Medicare's cost-based reimbursement system, which encouraged admissions and days and use of technologies even if there were few benefits. The PSRO review program often led to reductions in admissions and lengths of stay, but when the costs of the program are taken into account, it is not clear that it saved Medicare costs.

Under Medicare's new DRG hospital payment system, hospitals continue to have financial incentives to increase admissions, but they also have incentives to reduce lengths of stay and technology use for inpatients. In order to be paid by Medicare, participating hospitals are required to contract by November 15, 1984, with utilization and quality control peer review organizations (PROs), which will monitor hospital admissions, lengths of stay, and use of technologies. The focus of the PRO review program has changed from that of the PSRO program to reflect the incentives of the new payment system. **Like PSROs, PROs will review hospital admissions for overuse.** In addition, however, **PROs must specifically monitor cardiac pacemaker implantations and reimplantations for possible overuse. PROs will also be more concerned than PSROs were with reviewing short lengths of stay and eventually with underuse of ancillary services.**

Medical devices have been most directly regulated through provider regulation by the State certificate-of-need (CON) laws passed in response to the National Health Planning and Resources Development Act of 1974 (Public Law 93-641). These regulations sought to reduce expensive duplication of technology and to ensure access to facilities. By 1983, all States except one (Louisiana) had passed CON laws, but only 23 were in compliance with Federal requirements in 1984. Because of uncertainty about the future of the Federal health planning program, the current continuing resolution stipulates that noncomplying States are not to be penalized.

Photo credit: U.S. Veterans Administration

The VA Prosthetics Center was involved in developing most of the prosthetic limbs and fitting techniques used today.

Institutions such as hospitals, nursing homes, kidney disease treatment centers, and ambulatory surgical centers are required to obtain a CON from a State or State planning agency for capital expenditures that exceed a minimum threshold, substantially change bed capacity, or substantially change services. Medical research institutions and health maintenance organizations (HMOs) are given special consideration. Although State laws may cover investments in other locations, only nine States cover equipment purchases for physicians' offices. **Few devices have been expensive enough to meet the threshold for CON review,** which is now $600,000 for capital expenditures, $250,000 for annual operating costs from a change in services, and $400,000 for major medical equipment. Under the higher limits that have been proposed, fewer devices would come under review.

Evidence on the effect of CON laws on the adoption of medical devices has been inconclusive. Early studies indicated that numbers of hospital beds fell, but investment and assets per bed, which relate to devices, rose. This result is consistent with the CON emphasis on bed supply and the high thresholds for review. There is no indication that CON has controlled medical costs. This finding is not surprising, because a CON agency has no limit on the annual capital expenditures that it may approve and does not consider operating costs, total costs, or use of devices and other technologies. The program was also charged with often-conflicting goals of controlling cost and assuring access, and relied on consensus among decisionmakers with different interests. It is possible, however, that CON procedures may have deterred applications and purchases.

The different incentives for hospitals under DRG payment have implications for CON laws. Some of the change depends on how capital expenses are handled under the DRG system. Under DRG payment, hospitals themselves may increasingly have financial incentives to adopt cost-reducing devices and to examine carefully cost-raising ones. And DRG payment has strengthened the incentive for providers to locate and use equipment and facilities outside of the more constrained inpatient setting in such sites as ambulatory diagnostic centers or physician offices.

Several approaches could be taken to deal with the shortcomings of the CON process. **Congress could expand the scope of CON regulation to cover purchases of equipment in all locations, or it could place a limit on the annual level of capital expenditures that CON agencies could approve. Alternatively, Congress could eliminate the CON requirement from the National Health Planning Act.**

Veterans Administration Policies Regarding Medical Devices

With 172 medical centers, an annual budget of about $1.3 billion for equipment and supplies, and an R&D budget of almost $160 million, **the VA has the potential to exert substantial influence in the market for medical devices, especially the market for rehabilitative devices.**

Rehabilitation R&D in the VA is intended to improve the quality of life and to further the independence of physically disabled veterans. The program has stressed developing practical devices and increasing the availability of new devices on the market, especially in prosthetics, sensory aids, and devices related to spinal cord injuries. In the past, the VA Prosthetics Center was involved in developing most of the prosthetic limbs and fitting techniques used today and in demonstrating uses of electric wheelchairs, which were then adopted by manufacturers. In recent years, funding has shifted toward intramural projects, such as rehabilitation R&D centers, which are affiliated with leading engineering schools. Adjusted for inflation, VA funds committed to R&D in rehabilitative devices have been stable or declining.

Responsibility for testing and evaluating medical devices is divided among several VA organizational units. Despite the opportunity that the VA system presents to test devices under actual conditions of use, problems of coordination among units and of adherence to evaluation protocols have hampered field testing of rehabilitative devices at VA medical centers.

The Testing and Evaluation Staff in Hines, IL, is responsible for testing nonrehabilitative devices, mainly standard stock items and smaller medical equipment. These evaluations, which are aimed at validating manufacturers' claims, consist mainly of consumer research efforts. Although VA regulations prohibit explicit comparison of different products, some evaluations of classes of devices have been attempted. These evaluations are used by purchasers of devices inside and outside of the VA system.

Through the VA Marketing Center in Hines, which manages and negotiates the VA's national purchasing contracts, the VA has a substantial position in the markets for medical equipment and supplies. Procurement by the VA Marketing Center has accounted for 5 to 10 percent of the national sales of X-ray, nuclear diagnostic, hemodialysis, and patient monitoring equipment. And the VA has enhanced its market leverage by contracting for the U.S. Public Health Service, the Department of Defense, and other Government agencies. The VA's market power has allowed the VA to obtain favorable prices on medical supplies through its centralized procurement channels.

VA medical centers purchase about 34 percent of their supplies through centralized procurement programs run by the VA or the General Services Administration. However, the medical centers have increasingly made purchases on the open market rather than through central supply channels, their open market purchases having risen from 10 percent of total purchases in the early 1960s to 39 percent in 1982. **The VA medical centers' reduced use of central purchasing prevents the VA from taking advantage of lower prices available through greater device standardization and volume purchases.**

The patterns of adoption and use of devices by the VA health system are conflicting. Some types of major medical equipment, such as CT scanners, may have been adopted by the VA less than warranted because of political pressures to contain costs. On the other hand, by statute, the provision of prosthetic devices to eligible veterans is unlimited. The VA's plan to set the budgets of medical centers on the basis of DRGs may distribute funds more rationally. This DRG system bears monitoring as it is implemented for issues of quality assurance and treatment of capital expenses.

Congressional options to improve VA policies towards medical devices could focus on specific areas, such as increasing research for longer term development of rehabilitative devices and expanding field testing of rehabilitative devices. Congress could also require the VA to move in the direction of undertaking more comparative evaluations of devices and increasing centralized procurement to take advantage of lower prices.

Conclusions

Since the purpose of the Medical Device Amendments of 1976 is to protect public health and safety, assessment of the law and potential changes in the act or its implementation cannot proceed without systematic information on the hazards associated with device use. Such information is now lacking. Available evidence indicates that the medical devices industry has not been systematically affected by regulation of marketing by FDA, insofar as companies have continued to be profitable and innovative and to enter the field. However, small manufacturers of contact lenses have had particular problems.

The medical devices industry has responded to incentives in the market, especially those from payment policies. As a result, the market has generally rewarded attention to technological sophistication but not to price or cost-consciousness and has fostered the development of devices used in acute care rather than in prevention and rehabilitation. Medicare's new method of paying hospitals on the basis of DRGs has the potential for cost containment and efficiency by providing incentives for providers, and hence manufacturers, to become more cost conscious.

At the same time, Medicare's DRG payment system raises important concerns: assurance of quality of care when providers have a financial incentive to minimize the use of technologies including devices, and possible inefficiencies if devices are purchased and used in locations less financially constrained than hospitals. The appropriate role of the CON program is tied to how capital expenses are handled under the DRG payment system. In any case, issues of access to devices for low-income and sparsely populated areas will remain. And as health insurance coverage and payment become more constrained, the concept of orphan devices may require more precise definition. The VA has the potential to use its leverage in the market, especially for rehabilitative devices, to channel development and commercialization into orphan devices with substantial social need and worth.

2.

Characteristics of the Medical Devices Industry

> An initial invention, however dramatic, needs many refinements before it is of widespread use. In the commercialisation of technology, the tortoises who carry out these refinements often beat the hares.
>
> —*The Economist*

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2.
Characteristics of the Medical Devices Industry

INTRODUCTION

In recent decades, the industry that manufactures medical devices has experienced continuous growth and change. As increased health insurance coverage has expanded purchasing power for medical care, the market for medical devices has grown correspondingly. Growth has occurred not only in the number of companies and employees working in the field, but also in the range of products developed and marketed. Throughout all facets of medical care—from diagnostic imaging and surgery to dentistry and optometry—devices unknown a generation or even a decade ago are now part of routine practice.

This chapter presents the most notable features of the medical devices industry. Besides the dynamic nature of the field, several themes emerge. One is great diversity, both in the medical devices that are marketed and in the companies that make them. Underlying the diversity in products is the high level of innovation. Another theme is that, more than in many other U.S. industries, small firms are particularly important in developing and producing medical devices. U.S. medical devices appear to be quite competitive internationally. Despite the diversity in companies and products, however, the concentration of production in medical devices is about the same as it is in a typical industry, i.e., a relatively small number of companies account for a sizable share of the market.

GROWTH IN THE MEDICAL DEVICES INDUSTRY

During the past 25 years, sales (value of shipments) of products in the five Standard Industrial Classification (SIC) codes representing medical devices have grown from less than $1 billion to more than $17 billion, an annual increase of more than 12 percent (table 1). The growth has been enormous, even when expressed in real dollars, which are intended to take account of price changes[1] (table 2). By 1982, sales in real dollars had reached six times the 1958 level, having risen at an average annual rate of 8 percent.

Growth in sales appears to have accelerated after 1963, a period which coincided with the early years after implementation of the Medicare and Medicaid programs in 1966. From 1966 to 1982, total U.S. expenditures on personal health care in real dollars grew at an average annual rate of 5 percent, and those of the Medicare program alone at 18.5 percent.

Although the start of Medicare and Medicaid was the most notable change, both private and public third parties have accounted for an increasing share of the growing expenditures on personal health care—from 35 percent in 1950 (12 percent private, 12 percent State and local, 10 percent Federal) to 51 percent in 1966 (25 percent private, 12 percent State and local, 13 percent Federal) and 69 percent in 1982 (28 percent private, 11 percent State and local, 29 percent Federal) (128). Although the exact relationship has not been documented, growth in health care expenditures expanded the market for products such as medical devices that are used in the course of delivering that care (see ch. 3).

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[1] Like most price indexes, those of the Department of Commerce measure annual price changes in a market basket of devices that were specified in 1972 (369). A common problem with such indexes is their inability to take into account price changes associated with the introduction of new products and with changes in product quality. This problem is particularly acute for medical devices, which have experienced constant and dramatic change.

Table 1.—Current Dollar Value of Shipments of Medical Devices by SIC Code, Selected Years 1958-83[a]

	Current dollar value of shipments (in millions)						Annual percentage change[b]					
Year	X-ray and electro-medical equipment (SIC 3693)	Surgical and medical instruments (SIC 3841)	Surgical appliances and supplies (SIC 3842)	Dental equipment and supplies (SIC 3843)	Ophthalmic goods (SIC 3851)	Total	X-ray and electro-medical equipment	Surgical and medical instruments	Surgical appliances and supplies	Dental equipment and supplies	Ophthalmic goods	Total
1983[c]	$5,500	$4,590	$3,140	$1,180	NA[d]	$17,410[e]	21%	12%	9%	7%	—	13%[e]
1982	4,557	4,114	5,642	1,107	$1,358	16,778	42	30	19	-16	8	23
1981	3,203	3,158	4,734	1,314	1,263	13,672	27	17	23	5	4	18
1980	2,527	2,697	3,861	1,252	1,212	11,549	10	14	14	17	8	13
1977	1,885	1,833	2,597	787	972	8,074	34	14	12	14	11	16
1972	444	962	1,454	409	568	3,837	14	15	12	13	6	12
1967	233	475	838	221	426	2,193	13	14	9	11	12	11
1963	144	284	597	148	273	1,446	9	17	5	5	7	8
1958	95	130	462	116	194	997	—	—	—	—	—	—

[a] For a listing of products in the Standard Industrial Classification (SIC) codes used, see table 7.

[b] For inconsecutive years, the compound annual growth rate, the annual rate of growth that makes the present value compound forward to equal a specified future value, was calculated.

$\%\Delta = [(FV/PV)^{1/N} - 1]\ 100$, where

$\%\Delta$ = compound annual growth rate
FV = future value (the value at the end of N compounding periods,
PV = present value
N = total number of compounding periods

[c] Preliminary estimates.

[d] NA indicates information not available.

[e] Total does not include shipments of ophthalmic goods.

SOURCES: U.S. Department of Commerce, Bureau of Industrial Economics, Capital, Energy, and Productivity Studies Division, Washington, DC, unpublished data, January 1984; P. Marcus, U.S. Department of Commerce, Washington, DC, personal communication, January 1984; U.S. Department of Commerce, Bureau of the Census, *1982 Census of Manufactures*, Preliminary Report Industry Series, MC82-I-36F-3(P), MC82-I-38B-1(P), MC82-I-38B-2(P), MC82-I-38B-3(P), MC82-I-38B-4(P), 1984; and E. Arakaki, U.S. Department of Commerce, Washington, DC, personal communication, August 1984.

Table 2.—Real (1972) Dollar Value of Shipments of Medical Devices by SIC Code[a], Selected Years 1958-83

Year	Real (1972) dollar value of shipments (in millions): X-ray and electro-medical equipment (SIC 3693)	Surgical and medical instruments (SIC 3841)	Surgical appliances and supplies (SIC 3842)	Dental equipment and supplies (SIC 3843)	Ophthalmic goods (SIC 3851)	Total	Annual percentage change[b]: X-ray and electro-medical equipment	Surgical and medical instruments	Surgical appliances and supplies	Dental equipment and supplies	Ophthalmic goods	Total
1983[c]	$2,145	$2,050	$2,975	$540	NA[d]	$7,710[e]	15%	7%	7%	2%	—	9%[e]
1982	1,858	1,915	2,790	528	$757	7,848	35	21	19	-20	8	18
1981	1,374	1,587	2,337	659	704	6,661	14	6	16	-4	-4	9
1980	1,210	1,494	2,007	685	735	6,131	-1.7	5	7	7	1	4
1977	1,274	1,273	1,649	564	707	5,467	23	6	3	7	4	7
1972	444	962	1,454	409	568	3,837	7	11	10	12	3	9
1967	311	568	920	234	479	2,512	9	11	7	10	11	9
1963	217	377	705	160	312	1,771	8	15	5	4	6	7
1958	150	184	549	130	231	1,244	—	—	—	—	—	—

[a] For a listing of products in the SIC categories used, see table 7.

[b] For inconsecutive years, the compound annual growth rate, the annual rate of growth that makes the present value compound forward to equal a specified future value, was calculated.

$\%\Delta = [(FV/PV)^{1/N} - 1]\ 100$, where $\%\Delta$ = compound annual growth rate
FV = future value (the value at the end of N compounding periods)
PV = present value
N = total number of compounding periods

[c] Preliminary estimates.

[d] NA indicates information not available.

[e] Total does not include shipments of ophthalmic goods.

SOURCES: U.S. Department of Commerce, Bureau of Industrial Economics, Capital, Energy, and Productivity Studies Division, Washington, DC, unpublished data, January 1984; P. Marcus, U.S. Department of Commerce, Washington, DC, personal communication, January 1984; M. Pavliscak, U.S. Department of Commerce, Washington, DC, personal communication, June 1984; and E. Arakaki, U.S. Department of Commerce, Washington, DC, personal communication, August 1984.

All segments of the medical devices industry have benefited from this growth, some more than others (tables 1 and 2). Most medical devices fall into one of five SIC codes of the Department of Commerce: 3693, X-ray, electromedical, and electrotherapeutic equipment; 3841, surgical and medical instruments; 3842, orthopedic, prosthetic, and surgical appliances and supplies; 3843, dental equipment and supplies; and 3851, ophthalmic goods.[2]

In both current and real dollars, sales of products in SIC codes 3693, 3841, and 3842 are much greater than sales of dental equipment and supplies and ophthalmic goods. Not only are sales in these three codes the largest in absolute terms, but they have also experienced the highest rates of increase, especially since 1980. SIC 3842 (surgical appliances and supplies), the category with the greatest sales, has had the highest growth rates, followed closely by SIC 3693 (X-ray, electromedical, and electrotherapeutic equipment). The tremendous growth in SIC 3693 from 1972 to 1977 may be somewhat overstated; in 1977, products misclassified in other SIC codes, mainly 3841, were assigned to 3693 (393).

Increases in the number of companies (firms) and establishments (plants) have paralleled the increases in sales (see table 3). From 1963 to 1982, SIC 3693 (X-ray and electromedical equipment), with annual rates of about 7 and 8 percent respectively, experienced the greatest rate of increase in companies and establishments. During this period, the other four SIC codes had annual increases ranging from about 2 to 6 percent. In all five medical devices codes, firms entering a field have thus exceeded those exiting.

By 1982, employment in the establishments in the SIC medical devices codes had exceeded 200,000, a 68-percent increase over the 129,500 employed in 1972 (see table 4). SIC 3693 (X-ray and electromedical equipment) again had the greatest rates of increase, reflecting the huge growth in production and facilities during the decade.

Table 3.—Growth in Medical Device Companies, Establishments, and Employment by SIC Code[a], 1963-82

	1982 levels (number)			1963–1982 compound annual growth rate		
SIC industry segment	Companies	Establishments	Employment (thousands)	Companies	Establishments	Employment
Total	2,986	3,361	217.5	4.4%	4.0%	5.6%
SIC 3693: X-ray and electromedical equipment	205	260	49.2	7.1	8.2	11.5
SIC 3841: Surgical and medical instruments	767	858	57.4	5.9	5.8	7.3
SIC 3842: Surgical appliances and supplies	1,212	1,365	68.6	4.5	3.5	4.8
SIC 3843: Dental equipment and supplies	435	474	15.4	2.6	2.2	3.5
SIC 3851: Ophthalmic goods	367	404	26.9	3.0	3.0	1.5

[a] For a listing of products in the SIC categories used, see table 7.

SOURCES: U.S. Department of Commerce, Bureau of the Census, *1963 Census of Manufactures, Industry Series*, MC63-I-36E and MC63-I-38A, *1982 Census of Manufactures*, Preliminary Report Industry Series (Washington, DC: U.S. Government Printing Office, 1966 and 1984).

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[2] The most comprehensive statistics on the medical devices industry come from the Census of Manufactures, which is conducted by the Bureau of the Census in the Department of Commerce. The data relate to domestic production by U.S. and foreign companies operating in the United States. A complete census is conducted every 5 years and an Annual Survey of a sample in intervening years. Products are categorized by Standard Industrial Classification (SIC) codes. Establishments are assigned to SIC "industries" on the basis of their primary line of business. A 1980 sample of 1,891 manufacturing establishments registered with the Bureau of Medical Devices in the Food and Drug Administration (FDA) fell into 162 SIC codes: 47 percent into the 5 major medical devices codes, which included an average of 177 establishments per code; 37 percent into 25 other SIC codes, each with 10 or more establishments; and 16 percent into 132 other SIC codes, each with fewer than 10 establishments (393). It can therefore be inferred that the establishments in the five medical devices codes account for a greater volume of medical devices production than those in other codes. Nevertheless, data by establishment from the five medical devices SIC codes exclude some establishments and perhaps some devices of multiproduct establishments whose primary products fall into other categories.

In addition, the FDA sample lists 47 establishments in SIC 2831, biologicals (393). Diagnostic substances and other biologicals represent about 45 percent of all shipments in SIC 2831 (363), but the data are not sufficiently detailed to permit separation of these medical devices products from other biologics, such as blood and vaccines.

SIC data on product shipments, however, include shipments of all medical devices, both those produced by establishments classified in the five medical devices codes and those classified in other codes (393).

Table 4.—Number of Employees in the Medical Devices Industry by SIC Code[a], Selected Years 1958-83 (in thousands)

Year	X-ray and electro-medical equipment (SIC 3693)	Surgical and medical instruments (SIC 3841)	Surgical appliances and supplies (SIC 3842)	Dental equipment and supplies (SIC 3843)	Ophthalmic goods (SIC 3851)	Total
1983[b]	50.5	62.0	71.2	16.2	NA[c]	199.9[d]
1982	49.2	57.4	68.6	15.4	26.9	217.5
1981	41.5	54.6	64.9	17.4	26.4	204.8
1980	38.8	51.3	61.8	16.7	29.4	198.0
1977	30.9	43.2	53.9	16.3	30.0	174.3
1972	12.1	34.5	43.9	12.4	26.6	129.5
1967	7.9	22.0	35.2	10.2	25.6	100.9
1963	6.2	15.1	28.3	8.0	20.3	77.9
1958	5.3	10.3	24.2	7.2	18.2	65.2

[a] For a listing of products in the SIC categories used, see table 7.
[b] Preliminary estimates.
[c] NA indicates information not available.
[d] Total does not include employment in the ophthalmic goods industry.

SOURCES: U.S. Department of Commerce, Bureau of the Census, *Annual Survey of Manufactures*, Statistics for Industry Groups and Industries, for years 1958, 1963, 1967, 1972, 1977, and 1981; U.S. Department of Commerce, Bureau of Industrial Economics, *1984 U.S. Industrial Outlook* (Washington, DC: U.S. Government Printing Office, January 1984); and E. Arakaki, Department of Commerce, Washington, DC, personal communication, August 1984.

In 1982, about 3,000 companies (firms) with 3,400 establishments (plants) were manufacturing products in the five medical devices SIC codes (table 3). Although this information is the most comprehensive and most recent available, it excludes multiproduct establishments with primary products in other codes. Changes in employment may be used as a proxy for changes in numbers of companies and establishments. In 1980, 4,300 establishments were registered with the Food and Drug Administration (FDA) as being engaged in manufacturing medical devices (197).[3]

Available information from the Internal Revenue Service (IRS) indicates that the profit rates of medical devices companies have exceeded those of many other manufacturing industries (table 5). The IRS category 3845 (optical, medical, and ophthalmic goods) includes some firms that do not produce medical devices (optical instrument and lenses firms) and excludes some that do (if their principal line of business lies in a different category). Nevertheless, this category contains substantial numbers of firms whose principal activity is producing medical devices (26). Sales of electrical medical devices may represent a small fraction—perhaps at the most 10 percent—of IRS category 3698 (other electrical equipment) (26). Annual profit rates for both of these IRS categories ranged from 10 to 18 percent (26), higher than the 9 to 11 percent in total manufacturing. In 1980, firms in IRS category 3845 (optical, medical, and ophthalmic goods), with 12.7-percent return on assets, were more profitable than firms in similar products such as other electrical equipment, chemicals and allied products, and electrical and electronic equipment.[4]

By any of these measures—sales, companies, establishments, employment, or profits—the growth of the medical devices industry has far exceeded that of many other industries (table 6). For example, from 1963 to 1982, the output of the total manufacturing sector grew at an annual rate of 2.7 percent and employment at a 0.5-percent rate. Even chemicals and related products, electrical and electronic equipment, and instruments and related products—sectors with products similar to medical devices—achieved much lower annual increases in output (from 4.3 to 5.6 percent annually) and in employment (from 1.4 to 2.9 percent annually).

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[3] As explained in ch. 5, several entities besides medical devices manufacturers also register with FDA.

[4] According to data from Dun & Bradstreet, returns on assets (indicators of profits) for medical devices SIC codes have equaled or exceeded returns on assets in other fields (95). For example, from 1978 to 1980, returns on assets for SIC 3693 (X-ray, electromedical, and electrotherapeutic devices) ranged from 8.8 to 11.4 percent, compared with a range of 9.0 to 9.8 percent for the broader SIC category 36 (electrical and electronic machinery, equipment, and supplies.)

Table 5.—Percent Return on Assets[a] for Medical Devices and Selected Industries by IRS Category, Selected Years 1963-80

Year	Optical, medical and ophthalmic goods[b] (IRS 3845)	Other electrical equipment[c] (IRS 3698)	Total manufacturing (IRS 40)	Chemicals and allied products (IRS 17)	Electrical and electronic equipment (IRS 25)
1980	12.7%	11.0%	10.5%	11.2%	9.6%
1977	14.5	11.2	10.6	12.5	10.5
1972	13.1	9.6	8.8	11.3	7.7
1967	17.9	13.6	10.2	12.8	11.4
1963	12.1	12.9	10.2	14.0	9.5

[a] Percent return on assets $= \frac{\text{Net income (less deficit)} + \text{interest paid}}{\text{Total assets}}$

Net income (less deficit) equals "total receipts less total deductions" less "interest on State and local Government obligations" plus "constructive taxable income from related foreign corporations."

[b] The IRS minor industry 3645 (optical, medical and ophthalmic goods) includes firms that would be classified in SIC categories 383 (optical instruments and lenses), 384 (surgical, medical, and dental instruments and supplies), and 385 (ophthalmic goods).

[c] The IRS minor industry 3698 (other electrical equipment) includes firms that would be classified in SIC categories 361 (electric transmission and distribution equipment), 362 (electrical industrial apparatus), 364 (electric lighting and wiring equipment), and 369 (miscellaneous electrical machinery, equipment, and supplies).

SOURCES: U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1963, 1967, 1972, 1977, and 1980; *Corporation Income Tax Returns*, statistics of income, for years 1963, 1967, 1972, 1977, and 1980; *A General Description of the Corporation Source Book*, publication 647, revised June 1983.

Table 6.—Growth in the Output and Employment of Selected Industries, 1963-82

Industrial sector	1963-82 compound annual growth rate: Output	1963-82 compound annual growth rate: Employment
Total manufacturing	2.7%	0.5%
Chemicals and allied products	4.3	1.4
Electrical and electronic equipment . . .	5.6	1.5
Instruments and related products	5.6	2.9

SOURCES: U.S. Department of Commerce, Bureau of Industrial Economics, *1984 U.S. Industrial Outlook* (Washington, DC: U.S. Government Printing Office, January 1984); and V. Ketterling, U.S. Department of Commerce, Bureau of Industrial Economics, Washington, DC, personal communication, February 1984.

The Department of Commerce has ranked several of the medical devices SIC codes in the top 50 codes whose growth in 1984 is predicted to exceed their 1972-81 peak: 3842, orthopedic, prosthetic, and surgical appliances and supplies, as 9th; 3693, X-ray, electromedical, and electrotherapeutic equipment, as 11th; 3841, surgical and medical instruments, as 13th; 2831, biological products, as 24th; and 3843, dental equipment and supplies, as 47th (369).

DIVERSITY IN PRODUCTS

The devices included in the five major SIC codes illustrate the wide range of products, not only across codes but within each code as well (table 7). SIC 3842 encompasses disposable supplies such as surgical drapes and adult diapers as well as wheelchairs and prostheses. And together the different codes include pacemakers, hospital furniture, and materials for dentures.

Table 8 presents 1982 sales of selected medical devices to U.S. hospitals. These data are national estimates that IMS America, Ltd., has compiled for OTA from the purchases of a sample of hospitals. Because the IMS data include only devices that are purchased frequently enough to permit statistical estimation, many expensive devices that are rarely purchased by individual hospitals, such as computed tomography (CT) scanners, do not appear.

Almost half of personal health care expenditures in the United States relate to hospital care (128), and hospitals use devices more intensively than other health care settings. Thus, the data in table 8 give some indication of the size of the mar-

Table 7.—Products in the Medical Devices Industry by SIC Code[a]

SIC code/products

3693—X-ray, electromedical, and electrotherapeutic apparatus

- Irradiation (ionizing radiation) equipment, including X-ray, beta ray, gamma ray, and nuclear (medical, dental, industrial, and scientific)
  - Medical X-ray equipment:
    - Diagnostic
    - Therapeutic
  - Dental X-ray equipment
  - Industrial and scientific X-ray equipment, excluding gamma and beta ray equipment
  - X-ray equipment accessories
  - X-ray tubes (sold separately)
  - Parts for X-ray equipment (sold separately)
  - All other ionizing radiation equipment, including gamma and beta ray equipment, excluding accelerators, cyclotrons, etc.
  - Irradiation (ionizing radiation) equipment, including X-ray, beta ray, gamma ray, and nuclear (medical, dental, industrial, and scientific), n.s.k.
- Electromedical equipment, including diagnostic, therapeutic, and patient monitoring, but excluding ionizing radiation equipment
  - Diagnostic:
    - Electrocardiograph (ECG)
    - Electroencephalograph (EEG)
    - Electromyograph (EMC)
    - Ultrasonic scanning devices
    - Automated blood and body fluid analyzers
    - Audiological equipment
    - Endoscopic equipment (bronchoscope, cystoscope, proctosigmoidoscope, colonoscope, etc.)
    - Respiratory analysis equipment
    - All other diagnostic equipment
  - Therapeutic:
    - Pacemakers
    - Defibrillators
    - Electrosurgical equipment
    - Diathermy apparatus (short wave and microwave)
    - Dialyzers
    - Ultrasonic therapeutic equipment
    - All other therapeutic equipment
  - Patient monitoring:
    - Intensive care/coronary care units, including component modules such as temperature, blood pressure, and pulse
    - Perinatal monitoring
    - Respiratory monitoring
    - All other patient monitoring equipment
  - Surgical support systems:
    - Heart-lung machines, excluding iron lungs
    - Blood-flow systems
    - All other surgical support systems
  - Parts and accessories for diagnostic, therapeutic, monitoring, and surgical support systems (sold separately)
  - Electromedical equipment, including diagnostic, therapeutic, and patient monitoring, but excluding ionizing radiation equipment, n.s.k.
- X-ray, electromedical and electrotherapeutic apparatus, n.s.k., typically for establishments with more than 5 employees

SIC code/products

- X-ray, electromedical and electrotherapeutic apparatus, n.s.k., typically for establishments with less than 5 employees

3841—Surgical and medical instruments and apparatus

- Surgical instruments, including suture needles, and eye, ear, nose, and throat instruments
- Orthopedic instruments, such as bone drills and bone plates, excluding eye, ear, nose, and throat instruments
- Diagnostic apparatus:
  - Metabolism and blood pressure
  - Optical diagnostic
  - Other
- Syringes:
  - Other than hypodermic
  - Hypodermic:
    - Uniquely designed for prefilling
    - Other
  - Hypodermic needles
  - Anesthesia apparatus, instruments, and parts
  - Oxygen tents
  - Veterinary instruments
  - Blood transfusion and intravenous equipment
  - Blood donor kits
  - Mechanical therapy appliances and parts thereof
  - Other surgical and medical instruments
  - Surgical and medical instruments, n.s.k.
- Hospital furniture, excluding beds and chairs
  - Operating room furniture, including tables, cases, cabinets, etc.
  - Patient room furniture, including cabinets, overbed tables, desks, dressers, etc., but excluding beds and chairs
  - Other hospital furniture, excluding operating and patient room furniture, beds, and instruments, but including cases, tables, bassinets, chart racks, backrests, etc.
  - Hospital furniture, n.s.k.
- Surgical and medical instruments, n.s.k. typically for establishments with 5 employees or more
- Surgical and medical instruments, n.s.k., typically for establishments with less than 5 employees

3842—Surgical appliances and supplies

- Surgical, orthopedic, and prosthetic appliances and supplies
  - Orthopedic appliances (braces), including parts
  - Sterilizers (hospital and surgical), excluding dental sterilizers
  - Surgical dressings:
    - Bandages, elastic
    - Bandages, other, including muslin, plaster of paris, etc. but excluding self-adhering bandages
    - Adhesive plaster, medicated and nonmedicated, including self-adhering bandages
    - Gauze (absorbent and packing)
    - Cotton, including cotton balls (sterile and nonsterile)
    - Other surgical dressings, including sponges, compresses, pads, etc.
  - Disposable surgical drapes, including O/B and O/R packs
  - Disposable incontinent pads, bed pads, and adult diapers
  - Sterile surgical sutures:
    - Absorbable
    - Nonabsorbable
  - Artificial limbs (prosthetic), including parts
  - Elastic stockings

Table 7.—Products in the Medical Devices Industry by SIC Code—continued

SIC code/products

  - Elastic braces, suspensories, and other elastic supports
  - Arch supports and other foot appliances
  - Corn remover pads, bunion pads, etc.
  - Breathing devices, excluding anesthetic apparatus but including incubators, respirators, resuscitators, inhalators, etc.
  - Surgical corsets
  - Crutches, canes, and other walking assistance devices
  - Splints and trusses
  - Wheel chairs
  - Other surgical orthopedic, and prosthetic appliances and supplies
  - Surgical, orthopedic, and prosthetic appliances and supplies, n.s.k.
- Personal industrial safety devices
  - Respiratory protection equipment, including gas masks, abrasive masks, canister masks, etc.
  - Eye and face protection devices, including face shields, hoods, and welding helmets and masks, but excluding industrial goggles and eye protectors
  - Protective clothing, except shoes
  - First aid snake bite and burn kits, both household and industrial types
  - Other personal safety devices
  - Personal industrial safety devices, n.s.k.
- Hearing aids, electronic:
  - Hearing aids, electronic
- Surgical appliances and supplies, n.s.k., typically for establishments with 5 employees or more
- Surgical appliances and supplies, n.s.k., typically for establishments with less than 5 employees

3843—Dental equipment and supplies

- Dental metals:
  - Precious
  - Nonprecious
- Dental alloys for amalgams
- Teeth, excluding dentures:
  - Porcelain
  - Other, including resinous and plastic
- Denture-base materials
- Dental chairs
- Instrument delivery systems (dental units)
- Dental hand pieces
- Other dental professional equipment, except X-ray
- Dental laboratory equipment, including furnaces, casting machines, lathes, benches, polishing units, flasks, blowpipes, presses, etc.
- Dental hand instruments (forceps and pliers, brosches, cutting instruments, etc.)
- Burs, diamond points, abrasive points, wheels, disks, and similar tools for use with hand pieces
- Dental cements and other non-metallic filling materials
- Waxes, dental gypsums, and other consumable supplies
- Other dental products including sterilizers, but excluding X-ray equipment
- Dental equipment and supplies, n.s.k., typically for establishments with 5 employees or more
- Dental equipment and supplies, n.s.k., typically for establishments with less than 5 employees

3851—Ophthalmic goods

- Ophthalmic fronts and temples
  - Fronts, finished (with or without decoration), and temples:
    - Gold filled fronts (full rimmed, semirimless, or rimless)
    - Aluminum and other base metal fronts
    - Plastic fronts
    - Combination fronts
  - Temples, all types
  - Ophthalmic fronts and temples, n.s.k.
- Glass ophthalmic focus lenses
  - Single vision lenses (ground and polished and moulded blanks)
  - Multifocal lenses:
    - Bifocals
    - Trifocals and double segments
  - Glass ophthalmic focus lenses, n.s.k.
- Plastic ophthalmic focus lenses
  - Single vision lenses
  - Multifocal lenses
  - Plastic ophthalmic focus lenses, n.s.k.
- Contact lenses
  - Conventional (hard)
  - Soft
  - Contact lenses, n.s.k.
- Other ophthalmic goods, n.e.c.
  - Centers, oxfords, parts, trims, etc.
  - Ophthalmic spectacles and eyeglasses (frames and mountings of all types when sold with corrective lenses inserted, with or without decoration)
  - Industrial goggles, eye protectors, welding circles and plates, mountings, and parts
  - Sun or glare glasses and sungoggles, ready-made
  - Nonfocus fashion tinted lenses, plastic and glass
  - Other ophthalmic goods and accessories (sunglass frames, single readers and magnifiers, holders, gas mask inserts, etc.)
  - All other ophthalmic goods, n.s.k.
- Ophthalmic goods, n.s.k., typically for establishments with 5 employees or more
- Ophthalmic goods, n.s.k., typically for establishments with less than 5 employees

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[a] n.e.c.—Not elsewhere classified.
n.s.k.—Not specified in kind.

SOURCE: U.S. Department of Commerce, Bureau of the Census, *Annual Survey of Manufactures*, Statistics for Industry Groups and Industries, 1977.

Table 8.—Sales of Selected Medical Devices to Hospitals by SIC Code, 1982

SIC code/product	Sales to hospitals (thousands of dollars)
X-ray and electromedical equipment (SIC 3693)	
X-ray supplies	$ 777,366
Radiological catheters and guide wire	135,878
Pacemakers and other cardiovascular products	499,999
Electrosurgical supplies	48,552
Surgical and medical instruments (SIC 3841)	
Surgeons' needles	4,310
Blood collection supplies	57,845
Thermometers	31,426
Surgical instruments	294,284
Syringes and needles	331,054
Catheters, tubes, and allied products	235,445
Diagnostic instruments	69,549
Surgical appliances and supplies (SIC 3842)	
Sutures	286,635
Ostomy products	13,842
Surgical packs and parts	174,123
Maternity products	26,869
Dialysis supplies	97,677
Cardiopulmonary supplies	71,176
Sponges	174,768
Bandages, dressings and elastic	172,303
Orthopedic supplies	302,283
Parenteral supplies	701,106
Urological products	198,970
Sterilizer supplies	88,846
Cast room supplies	39,836
Disposable kits and trays	258,317
Respiratory therapy	245,890
Garments, textiles, and gloves	592,254
Ophthalmic goods (SIC 3851)	
Ophthalmic-related products	83,649
Other	
Solutions	872,985
Medical supplies	420,702
Chemicals and soaps	153,946
Paper products	113,738
Gases	109,933
Underpads	55,259
Identification supplies	31,517
Elastic goods	24,932
Rubber goods	7,281
Total	$7,804,545

SOURCE: IMS America, Ltd., Rockville, MD, unpublished data, 1983.

ket for different devices. The highest sales to hospitals are of disposable or nondurable items, such as X-ray supplies and garments, textiles, and gloves. For many of the devices with high sales volumes, hospitals account for only a portion of the overall market. For example, parenteral supplies (for feeding through the bloodstream rather than the alimentary canal) are increasingly used in home health care (see ch. 3) and X-ray supplies are also purchased by independent diagnostic centers and private offices.

Nondurable products are even more prominent among the medical devices in a physician's office. Table 9 lists the medical devices in an office of two internists practicing in an urban setting. Although the office contains basic medical furniture and equipment, most of the products are disposed of after one use.

CHARACTERISTICS OF MEDICAL DEVICES MANUFACTURERS

As indicated by table 3, the number of device companies is almost as large as the number of establishments, with an average of 1.13 establishments per company. This relationship implies that the mode in the medical devices industry is a company with one plant, although larger companies are likely to have multiple plants. This pattern appears to be similiar to that in other industries. For industries in which the four leading firms accounted for between 40 and 64 percent of market sales, a situation similar to that in the medical devices industry, the four leaders in 1963

Table 9.—Medical Devices in an Internist's Office

Medical fixtures:
- (examining tables and other fixtures used for medical purposes)
- Examination rooms (2)
  - 2 exam tables with stirrups and storage drawers
  - 2 scales
  - 1 treatment cabinet (large)
  - 1 instrument cabinet (small)
  - 1 eyechart
- Laboratory
  - 1 X-ray view box
  - 1 test tube rack
  - 1 sedimentation tube rack

Medical office supplies:
- 1 hanging medical record cabinet (7 tiers)
- Manila chart folders
- Printed forms for charts
- Prescription blanks
- Color-coded medical record stickers

Diagnostic supplies:
- Cover slides
- Urinalysis plastic cups
- Wipes for urinalysis clean catch
- Table paper
- Drapes
- Paper tape
- Bili lab stix (dip-urinalysis)
- K-Y jelly
- Pregnancy test kit (urinary chorionic gonadotrophins (UCG)-Beta slide)
- Sedimentation tubes, cotton plug
- Stains (Gran's iodine-safranin, etc.)
- Throat culture plates (oxblood 5%)
- Discs for throat cultures (Taxo A)
- Uricults
- Hemoccult slides (single and triple)
- Electrocardiograph (EKG)-mounting paper, electro pads & electrode cream
- Sani vaginal specs size (S)
- Sani vaginal specs size (M)
- Anoscopes
- Cards for tuberculosis test
- Sclavotest purified protein derivative (PPD) tuberculosis test
- Patient gowns (cloth)
- Cloth tape measures
- Thermometers
- Gonococcus culture plates
- Blood drawing tubes
- Alcohol wipes
- Sterile swabs
- Swabs
- Baggies
- Cervi scrapes
- Fixative spray for Pap slides
- Slides (wet mount for Pap)
- Cardboard containers for Pap slides
- Culturettes
- Gloves (med Tru-touch)
- Request slips for tests

Therapeutic supplies:
- Gauzes
- Syringes
- Peroxide
- Alcohol
- Betadine scrub
- Cidex 7 (long life)
- Drug samples
- Bandaids

Diagnostic equipment:
- Examination rooms (2)
  - 2 wall model Baumanometer blood pressure instruments (3 cuffs)
  - 1 EKG machine
  - 2 Burton exam lamps
  - 2 otoscope/ophthalmoscope desk units
- Laboratory
  - 1 centrifuge (provided on load by lab)
  - 1 microscope
  - 1 incubator

Therapeutic equipment:
- Instruments (minor surgical--i.e., scissors, scalpels, tweezers, etc.)

SOURCE: R. Berenson, Washington, DC, personal communication, January 1984.

averaged 4.7 establishments per company and the next four, 2.4 establishments per company; but the remaining firms averaged only 1.08 establishments per company (274).

In 1977, medical devices establishments averaged 54 employees, about the same as the 53 employees per establishment for all manufacturing (362). Within the medical devices field, SIC 3693 (X-ray and electromedical equipment) had the largest average size establishment with 127 employees, and SIC 3843 (dental equipment) had the smallest with 30 employees (table 10).

Despite the growth that has occurred in medical devices in recent years, there have not been major increases in the average size of an establishment. In fact, for all of the major medical devices SIC codes except X-ray and electromedical equipment and dental equipment, average employee size fell from 1972 to 1977; for SIC 3693 (X-ray and electromedical equipment), it rose from 116 to 127 employees per establishment, and for SIC 3843 (dental equipment), it rose from 29 to 30 employees per establishment (362). From these statistics, one may infer that, with the possible exception of X-ray and electromedical equip-

Table 10.—Size of Employment in Medical Devices Establishments by SIC Code, 1977

	Number of establishments by employee size				Percentage of all establishments by employee size				Average number of employees per establishment
SIC industry segment	1-19	20-99	100-499	≥ 500	1-19	20-99	100-499	≥ 500	
SIC 3693: X-ray and electro-medical equipment	117	55	55	16	48%	23%	23%	7%	127
SIC 3841: Surgical and medical instruments.........	412	147	72	19	63	23	11	3	66
SIC 3842: Surgical appliances and supplies	832	213	86	22	72	18	7	2	46
SIC 3843: Dental equipment and supplies	431	85	30	4	78	15	5	1	30
SIC 3851: Ophthalmic goods ..	479	98	50	7	76	15	8	1	47
Total	2,271	598	293	68	70%	19%	9%	2%	54

SOURCE: U.S. Department of Commerce, Bureau of the Census, *1977 Census of Manufactures, Industry Series*, MC 77-I-38B and MC 77-I-36F (Washington, DC: U.S. Government Printing Office, June 1980).

ment, growth has occurred through increases in the numbers rather than in the size of establishments.

Although small establishments dominate in number, they account for a much smaller fraction of total shipments in each SIC code (table 11), and these patterns have been extremely stable since 1963 (393). The extremes are again represented by X-ray and electromedical equipment and dental equipment. Among manufacturers of X-ray and electromedical equipment in 1977, establishments with fewer than 50 employees sold only 5 percent of all shipments, but those with 250 or more employees sold 71 percent of all shipments. In the dental equipment field, establishments with fewer than 50 employees sold 21 percent and those with 250 or more employees sold 46 percent of all shipments (393).

There is some evidence that larger medical devices establishments have higher profit rates than smaller ones. One indicator of profits is the difference between the cost of manufacturing a product and the price for which it is sold. Price-

Table 11.—Market Share of Value of Medical Devices Shipments by Establishment Size, 1977, 1972, and 1963

		Percentage of market share of establishments by employee size			
SIC industry segment	Total number of establishments	1-49	50-99	100-249	≥250
SIC 3693: X-ray and electromedical equipment					
1977	243	5%	5%	19%	71%
1972	104	7	4	20	69
1963	58	6	11	23	60
SIC 3841: Surgical and medical instruments					
1977	650	12	9	17	62
1972	506	11	11	21	57
1963	294	15	11	24	39
SIC 3842: Surgical appliances and supplies					
1977	1,153	13	8	16	63
1972	873	12	6	13	69
1963	704	12	8	11	69
SIC 3843: Dental equipment and supplies					
1977	550	21	8	25	46
1972	429	22	14	24	39
1963	316	23	20	21	36
SIC 3851: Ophthalmic goods					
1977	634	15	5	17	63
1972	494	12	7	17	64
1963	229	9	14	12	65

SOURCES: U.S. Department of Commerce, Bureau of the Census, *Census of Manufactures, Industry Series*, for years 1963, 1972, and 1977, as cited in Arthur Young & Co., *A Profile of the Medical Technology Industry and Governmental Policies*, final report, vol. 1, June 30, 1981.

cost margins have been calculated for medical devices establishments with data from the Census of Manufactures (table 12). According to these 1977 data, price-cost margins were highest for the largest establishments. In only two of the five codes, however, did the smallest sized establishments have the lowest margins. A serious problem with these figures is that they overstate profits because they exclude costs such as research and development, advertising, and depreciation (18).

Small companies in the medical devices field have a greater share of industry output than in manufacturing generally (26). Companies with one establishment account for 21 percent of all sales of medical instruments and supplies and 31 percent of optical and ophthalmic goods, but only 16 percent of all manufacturing.[5] Companies with fewer than 250 employees account for 25 percent of all sales of medical instruments and supplies and 32 percent of optical and ophthalmic goods as compared with 18 percent of all manufacturing.

The role of small firms in medical instruments and supplies is comparable to that of those in electronic components in terms of number of establishments or total receipts. If firm size is defined by number of employees, small medical instrument and supply firms with fewer than 250 employees account for a larger share of sales than firms of a similar size in the electronic components industry.

Table 12.—Price-Cost Margins[a] of Medical Devices Establishments by Employee Size, 1977

		Margins of establishments by employee size			
SIC industry segment	Total	1-49	50-99	100-249	≥ 250
SIC 3693: X-ray and electromedical equipment	0.406	0.374	0.275	0.398	0.422
SIC 3841: Surgical and medical instruments	0.394	0.326	0.360	0.368	0.420
SIC 3842: Surgical appliances and supplies	0.374	0.307	0.322	0.355	0.400
SIC 3843: Dental equipment and supplies	0.325	0.283	0.360	0.274	0.366
SIC 3851: Ophthalmic goods	0.352	0.350	0.297	0.351	0.357

[a] Price-cost margins are calculated from Bureau of the Census data as follows:

$$\text{Price-cost margin} = \frac{\text{Value added} - \text{Payroll}}{\text{Value of shipments}}$$

"Value added" is the value of shipments minus materials, supplies, energy and certain other input costs. It is defined by the Census on an establishment basis. Price-cost margins are just one measure of profitability; each different measure has advantages as well as disadvantages. Limitations of the price-cost margins are: 1) the margins are overstated proxies of profitability since the Census does not provide directly comparable estimates of non-plant costs such as advertising, central office costs, R&D, and plant depreciation, and 2) the margins are conceptually inadequate because they fail to account for the industry's capital intensity.

SOURCE: U.S. Department of Commerce, Bureau of the Census, *1977 Census of Manufactures, Industry Series*, as cited in Arthur Young & Co., *A Profile of the Medical Technology Industry and Governmental Policies*, final report, vol. 1, Washington, DC, June 30, 1981.

CONCENTRATION IN THE MEDICAL DEVICES INDUSTRY

The extent to which sales are concentrated among a few companies is a measure of the competitiveness of an industry. Despite the large number of companies, especially small ones, concentration in the five medical devices SIC codes is similar to that in other manufacturing industries. In 1977, the four leading firms accounted for 32 to 45 percent of the sales in the medical devices SIC codes (table 13). By comparison, in 43 percent of all U.S. manufacturing industries during 1972, the four leading firms had 40 percent or more of the total market (274). In the five medical devices codes, the share of the four or eight leading firms has been continually declining since

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[5] These data are compiled on the basis of companies rather than establishments. The category optical and ophthalmic goods includes products such as telescopes and other optical equipment and hence is broader than medical devices (26).

Table 13.—Market Share of Value of Medical Devices Shipments by Leading Companies, 1977 and 1963

SIC industry segment	Total number of companies	Percentage of market share: 4 leading companies	Percentage of market share: 8 leading companies
X-ray and electromedical equipment (SIC 3693)			
1977	212	32%	51%
1963	56	67	79
Surgical and medical instruments (SIC 3841)			
1977	575	32	48
1963	256	47	58
Surgical appliances and supplies (SIC 3842)			
1977	1,017	38	49
1963	525	49	58
Dental equipment and supplies (SIC 3843)			
1977	507	33	46
1963	267	37	50
Ophthalmic goods (SIC 3851)			
1977	593	45	56
1963	211	53	62

SOURCES: U.S. Department of Commerce, Bureau of the Census, *Census of Manufactures, Industry Series*, for years 1963 and 1977, as cited in U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, *Baseline Data on the Availability of Medical Devices and In-Vitro Diagnostic Products*, OPE Study 54, Washington, DC, 1980.

1963, with the possible exception of SIC 3841 (surgical and medical instruments), whose ratio increased slightly from 1972 to 1977.

As one would expect, the field appears to be much more concentrated at the level of more specific products. The 1977 Census of Manufactures reported the number of companies with shipments of $100,000 or more for each product line. SIC 3693 (electromedical equipment) had four product types with only one manufacturer, and SIC 3842 (surgical appliances and supplies) had one product with a single manufacturer (393). The products in the other SIC codes, which varied in their level of detail, all had more than one manufacturer, although the numbers were sometimes small.

Data from IMS America on sales to hospitals indicate that a small number of companies have a large share of the market for specific devices (table 14). For sutures, the four leading companies accounted for 99.9 percent of all sales. Market shares over 96 percent were also held by the four leading firms in surgeons' needles, blood collection supplies, and ostomy products (for discharge of intestinal contents or urine through an artificial opening). The lowest market shares of the four leaders, which were still substantial, were 43 percent for garments, textiles, and gloves and 45 percent for respiratory therapy devices. Several companies have large market shares across a range of products. As shown in table 15, American Hospital Supply Corp. is one of eight leading firms in 21 of the 28 product categories listed in table 14, and Johnson & Johnson is one in 14.

Prices for products in SIC medical devices codes have increased at rates comparable to those in other manufacturing industries. Available indexes measure price changes in a given market basket of products and do not incorporate new products or changes in old ones, a serious deficiency for the innovative medical devices field. From 1972 to 1982, product prices rose at an annual rate of 9.5 percent for SIC 3693 (X-ray and electromedical equipment), 8 percent for SIC 3841 (surgical and medical instruments), 7.3 percent for SIC 3842 (surgical appliances and supplies), 7.7 percent for SIC 3843 (dental equipment and supplies), and 5.9 for SIC 3851 (ophthalmic goods) (369, 375). During that time, product prices increased at an annual rate of 9.2 percent for all manufacturing industries and 6.7 percent for the electrical and electronic equipment industry.

The lower rate of price increase in ophthalmic goods is consistent with the case of contact lenses. From 1971 to 1982, the list price of soft contact lenses fell 50 percent, a result of competition among fitters as well as among producers of the lenses (275). The mature hard lens sector, which exhibits little evidence of economies of scale in production, has few dominant firms and has been highly price-competitive for several years. In the

Table 14.—Leading Companies' Market Share of Hospital Sales of Medical Devices, 1982[a]

SIC code/product	Sales to hospitals (thousands of dollars)	Percent market share	
		4 leading companies	8 leading companies
X-ray and electromedical equipment (SIC 3693)			
X-ray supplies	$77,366	89.3%	98.2%
Radiological catheters and guide wire	135,878	85.3	92.8
Pacemakers and other cardiovascular products	499,999	73.7	88.9
Electrosurgical supplies	48,552	58.9	82.6
Surgical and medical instruments (SIC 3841)			
Surgeons' needles	4,310	96.5	99.6
Blood collection supplies	57,845	96.4	99.1
Thermometers	31,426	78.8	92.3
Surgical instruments	294,284	68.1	81.2
Syringes and needles	331,054	65.7	80.9
Catheters, tubes and allied products	235,445	60.8	81.6
Diagnostic instruments	69,549	59.5	77.8
Surgical appliances and supplies (SIC 3842)			
Sutures	286,635	99.9	100.0
Ostomy products	13,842	97.9	99.6
Surgical packs and parts	174,123	84.1	95.1
Maternity products	26,869	82.3	91.8
Dialysis supplies	97,677	81.5	93.3
Cardiopulmonary supplies	71,176	79.4	98.0
Sponges	174,768	78.9	88.4
Bandages, dressings and elastic	172,303	77.3	87.5
Orthopedic supplies	302,283	74.5	83.8
Parenteral supplies	701,106	72.6	91.9
Urological products	198,970	71.7	86.8
Sterilizer supplies	88,846	71.4	83.5
Cast room supplies	39,836	62.2	78.6
Disposable kits and trays	258,317	46.7	63.1
Respiratory therapy	245,890	45.1	67.4
Garments, textiles, and gloves	592,254	43.7	61.1
Ophthalmic goods (SIC 3851)			
Ophthalmic-related products	83,649	67.9	93.3

[a] IMS America's Hospital Supply Index also has nine other categories that are not included here: elastic goods, identification supplies, solutions, chemicals and soaps, gases, medical supplies, paper products, rubber goods, and underpads.

SOURCE: IMS America, Ltd., Rockville, MD, unpublished data, 1983.

Table 15.—Eight Leading Companies in Hospital Sales of Medical Devices in Three or More Product Categories, 1982[a]

Company	Number of product categories in which company is one of eight leading companies	Company	Number of product categories in which company is one of eight leading companies
American Hospital Supply Corp.	21	Brunswick Corp.	4
Johnson & Johnson	14	Lilly	4
Colgate-Palmolive	8	Cordis/Cordis Dow	3
Baxter-Travenol	7	Dart Industries	3
Bard, C.R.	6	Independent Lab	3
Pfizer	6	Kimberly-Clark	3
Abbott	5	Professional Med. P.	3
Bristol-Myers	5	Squibb	3
Minnesota 3M Labs	5	Terumo-America Inc.	3
Becton Dickinson	4	Warner-Lambert	3

[a] Out of the 28 product categories listed in table 14.

SOURCE: IMS America, Ltd., Rockville, MD, unpublished data, 1983.

younger soft lens sector, the four leading firms control almost 70 percent of the market, but new firms have entered and the concentration level has declined steadily during the past 5 years.

There is some evidence that merger activity in the medical devices field accelerated during the latter part of the 1970s. Respondents to a survey in 1981 said that only 4 percent of their companies had been acquired by another firm, merged with another firm, or acquired another firm from 1972 to 1975, but 23 percent answered affirmatively for 1976 to 1980 (197). By 1982, 100 of the 140 firms belonging to the Pharmaceutical Manufacturers Association produced diagnostic products and other medical devices, accounting for an estimated 60 percent of all such sales (244).

INNOVATION IN MEDICAL DEVICES

A hallmark of the medical devices field has been the introduction of new products and the refinement of old ones. Some innovations affect ordinary devices that are used frequently, such as assembled surgical trays for operating rooms (2). Others represent the application of sophisticated technology to medical uses, such as nuclear magnetic resonance imaging.[6] This rapid innovation in medical devices has certainly underlain much of the growth in firms and sales in recent decades.

Although innovation in medical devices has not been precisely documented, striking evidence is provided by the changes in medical practice that have resulted from new medical devices. In boxes A and B, respectively, a pathologist and an ophthalmologist relate certain changes in clinical laboratories and ophthalmology that have been linked to innovations in devices. Innovative devices have been the basis for tremendous changes in clinical laboratory procedures. Compared to a generation ago, clinical laboratory tests can now be performed more accurately and quickly as well as with fewer, less skilled personnel and at lower cost.

The pace of innovation in ophthalmology described in box B is greater than one might expect from the relative growth of the SIC code 3851 (ophthalmic goods). However, many of the new or refined medical devices used in ophthalmology are surgical instruments or electromedical equipment, which appear in other SIC codes. Similar innovations have taken place in other areas of medicine, such as digital subtraction angiography and CT scanning in diagnostic imaging and pacemakers and materials for hip joints in surgery.

Patents are frequently used as a measure of innovative activity in an industry. Such data have limitations since not all inventions are patented, several patents may pertain to a single invention, and the propensity to patent is greater in some fields than in others.

The number of patents granted by the U.S. Patent Office grew modestly through the 1970s. From 1968 to 1979, almost 22,000 applications were filed for medical devices patents that were subsequently issued (table 16), representing 2 percent of all patents (381). Compared with all U.S. patents over the same period of time (see app. D, table D-2): 1) while all patents have remained essentially constant, medical devices patents increased moderately; and 2) while foreign-origin medical devices patents as a percent of total medical devices patents increased from 20 to 30 percent over the 1970s, foreign-origin patents for all U.S.-issued patents increased from about 30 to 40 percent. Individuals owned 37 percent of the medical devices patents, compared with 22 percent of all patents, an observation suggesting the important role of individuals in the medical devices field. Table 17 provides information on patenting activity in specific medical device fields (see app. D for further information on patents). Electrical systems and diagnostic equipment using radiation, for example, accounted for about 6 percent of all medical devices patents. Strength in this area is consistent with the rapid growth in sales, firms, and employment that has characterized the related segment of the medical devices industry (X-ray,

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[6] See the separately published OTA case study on nuclear magnetic resonance imaging by Steinberg and Cohen (291).

Box A.—Changes in the Clinical Laboratory[1]

In the 1950s, I saw the marvelous technique of Folin-Wu, which was used in those days in order to determine the patient's blood glucose level, or as it is more colloquially known, the blood sugar. This entailed the mixing of various chemicals in such a fashion as to cause after 45 minutes of smelly boiling, the development of a blue color whose intensity was an indication of the amount of sugar which was present in the patient's blood. It should be remembered that prior to this test, presence of glucose in the patient's urine was determined by tasting the urine and in fact, as is generally known, the term diabetes mellitus means sweet tasting and derives from the physician's diagnosis of excess sugar in the patient's system by the test of urine tasting. I suspect that in some parts of the world, Folin-Wu sugars are still being performed because they are cheap, work, and require only a basic knowledge of chemistry and simple laboratory equipment. This is in contrast to the methods which we now employ, which involve a sophisticated enzymatic reduction method. . . . In days past, the determination of the Folin-Wu sugar on 10 patients would entail a full morning's work for the skilled laboratory technologist in the pathology laboratory. Today, we can perform 150 glucose tests in 1 hour using the skills of a well-trained and educated high school graduate. The cost per test now is on the order of a few pennies and the cost per test 20 years ago was considered to be inexpensive at $5.00. . . .

The clinical diagnostic laboratory or Department of Laboratory Medicine is routinely accepted today as a vital component of modern health care. As recently as 30 years ago, however, that was not the case. What is now called a Department of Laboratory Medicine, or in some centers, clinical pathology, was then part and parcel of the Department of Pathology. There were no commercial clinical laboratories to speak of and you could count the number of manufacturers of capital laboratory goods on the fingers of one hand. If a physician wanted to know the quantity of sugar in the patient's blood, the test required about an hour and a half of preparation, boiling, and manipulation before an approximation could be given of the amount of glucose in the patient's blood—and in fact, we weren't measuring glucose; we measured reducing substances, that is, all of the sugar-like materials that were in the patient's blood. For that matter, there were very few constituents that we were able to chemically approximate just 30 years ago. . . .

Diagnostic biochemistry really began to flower in the 1950s and early 1960s when various enzymatic methods were discovered for the determination of specific sugars, such as glucose, and other determinations were developed for uric acid, urea nitrogen rather than the gross determination of nonprotein nitrogen, total protein, calcium and phosphorus, and other constituencies which appear to be useful in the daily management of patients who were ill and under stress. . . .

In mid-1950, Dr. Skeggs at Western Reserve University had a rather ingenious idea. He automated, for the first time in the clinical laboratory, the mixing, sampling and reading of the constituents in the patient's blood when he automated the blood sugar using the continuous-flow autoanalyzer. That first single-channel autoanalyzer was sold in 1957 by the Technicon Company. . . . With the invention and mass sale in the early 1960s of the single-channel autoanalyzer, it suddenly became possible to perform a series of tests virtually without regard for the cost of labor. . . .

In 1965, I recall being a first-year resident in pathology and witnessing the chief of the department bringing back the first SMA 12 in Pittsburgh to our hospital in his station wagon. We set it upon saw-horses. He and the administrator agreed that the instrument would not only provide 12 tests to the institution on every patient (at great savings) but would also provide a charge to the institution in 1965 dollars of $20.00 per evaluation. That is comparable in 1984 dollars to $65.34. . . .

It should also be pointed out that these instruments all used large quantities of reagants as did the continuous flow technology. This of course put the capital vendors into the reagent and parts business in a big way. In those days we did not have the microchemical procedures that later evolved in the mid-1970s, and have been extrapolated in the past few years to virtually all of the automated equipment which is used in the laboratory. Even if the cost of running these instruments was high and the purchase costs were large, when compared to the then available manual testing methods that were in vogue, these new instruments were a quantum leap forward in efficiency, quality, and quantity of data base. . . .

Where we had in the mid-1950s and early 1960s the rare professio[illegible] medical technologist performing reducing substances on the patient's blood manually at the rate of six tests per hour, by 1983 we had one registered medical technologist supervising the production of one machine which has the capability of performing 1,800 individual tests per hour. Where there was virtually no capital equipment cost to do the few sugars in 1960, the capital equipment cost in order to process the 2,300 samples per hour is on the order of $400,000.

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[1] Excerpted from a paper prepared for OTA by Lupovich (199).

Box B.—How Ophthalmology Has Changed During My Career[1]

Ophthalmology is practiced mostly in private offices, the majority of the work being primary care with attendant high-volume, low-disease rates, and the remainder at a tertiary level with great technical sophistication and high-risk, high-reward surgery. Here is a description of ophthalmological technology when I began my residency in 1956, and how it then changed. . . .

Measuring the refractive state of the eye is usually accomplished in two stages: objective and subjective. When I entered ophthalmology, the objective phase was almost invariably performed by the practitioner's using a small hand instrument called a retinoscope. In a darkened room, with the patient gazing at a distant small light source that would not encourage accommodation, the examiner peering through a sight-hole of the instrument along the axis of a light beam entering the patient's pupil, is able to gauge the nature of the optical system of the eye by the character of the small amount of light reflecting back from the patient's retina. . . .

Objective testing has changed significantly during my career. There are now nearly 20 optical-electronic devices commercially available for performing retinoscopy or some other very closely allied objective test. These can all be operated by technicians who need not have any skills in the traditional methods of refraction. . . .

Early in the 1950s, most sharp cutting instruments were still made of nonstainless steel, were hand-sharpened, and were used repeatedly. The cornea is extremely tough tissue to cut, and instruments for opening the cornea to begin cataract surgery presented a particularly difficult problem. If the point of such an instrument is only slightly dull, the surgeon must push it harder, and then it is likely to enter the eye in a rush. A great improvement has been made in recent years with the introduction of disposable blades. Each of these blades is very sharp, but, more important, they are predictable. The amount of force required to use them is always the same, and the surgeon knows what to expect.

Another important advance in ophthalmic instrumentation for surgery has been the development of better needles for suturing the ocular tissues. In the early 1950s, the needles were hand-honed, used repeatedly, and had eyes that required threading, like ordinary sewing needles. Placing sutures in the cornea with these needles did not allow great precision in apposition of the wound edges. Disposable needles swaged onto the ends of the suture made a great advance. By the late 1950s, the new generation of very sharp disposable swaged-on needles made placement of sutures a qualitatively different procedure. . . .

The next great changes in cataract surgery came about as the result of increased use of magnification. During the 1950s and 1960s, the operating microscope was a feature of every well-equipped ophthalmic operating room. However, the instrument was used primarily for corneal transplants, where a higher level of precision of technique was clearly advantageous. The microscope improved in response to the demands of the surgeons, and with improvements in the operating microscope the surgeons demanded finer and finer needles and sutures. . . . During the decade of the 1970s, the operating microscope became the standard for modern corneal and cataract surgery, and today it would be difficult to defend this type of surgery without the use of a first-class operating microscope. A good operating microscope today costs from $30,000 to $60,000 or $70,000, and with photographic and other optional attachments the price can go significantly higher. . . .

The first truly successful intraocular lens (IOL) implants were made of one rigid piece of plastic (methyl methacrylate) placed in the anterior chamber of the eye, under the vault of the cornea, and in front of the iris. . . . These lenses are still in use, but are falling into disfavor because the pressure of the lens against the tissues holding it causes disturbances that can be serious. . . . There was a great wave of enthusiasm for iris-supported lenses, but this began to wane about 2 or 3 years ago, when the reports of bad long-term results began to accumulate. . . . The next shift in IOL implants has been toward placing the IOL in the posterior chamber, the place behind the iris from which the patient's own natural lens has been removed . . . surgeons' choosing to put IOLs in the posterior chamber has revived the extracapsular operation, which leaves the posterior capsule in place to support the IOL.

From the moment that lasers appeared in our culture, it was obvious that their use in the eye was reasonable, because of the optical transparency of many of the ocular tissues. Sophisticated and very expensive machines are available from a number of companies that allow the ophthalmologist to deliver sufficient laser light to tiny areas of ocular tissue to create destructive burns. Carefully controlled, these burns can do many beneficial things. Without opening the globe, the laser can seal holes in the retina by creating "spot welds," thus avoiding the necessity for a full-blown retinal detachment operation. Areas of abnormal vessel growth can be treated to coagulate the vessels and to prevent hemorrhage or exudation of fluid from the vessels which might otherwise be very destructive. Within the last several years, the laser has developed a widespread use in the treatment of diabetic disease of the retina, diabetic retinopathy. . . .

The Neodymium YAG (yttrium aluminum garnet) laser creates invisible radiation in the infrared range, and has been used for 15 years or more by industry and the military. It can deliver very large amounts of power to a very small area, and is not dependent on the color of the tissue for the delivery of its energy. . . . Approximately 40 percent of patients who have extracapsular surgery will develop sufficient opacification of the posterior capsule so that a secondary procedure is required to create a clear pupil through which the patient can obtain good vision.

Until the introduction of the YAG laser, the only way to treat this opacification was by introducing a small cutting needle or knife into the eye at a second surgical procedure, and slitting the membrane. Posterior capsulotomy is safe, but it does involve re-entering the eye, and that is always to be avoided if possible. The YAG laser can deliver its energy to the posterior capsule and can easily cut holes in the posterior capsule, when no other available laser can do that. This procedure can be done in the office with the patient sitting at the slit lamp which has been adapted to guide the laser light into the eye. It is easy for the surgeon and the patient. The entire procedure frequently does not take five minutes. However, the laser may cost in the neighborhood of $80,000, and the procedure is remunerated at the same rate as a surgical capsulotomy, which has been classically remunerated at the high rates that are afforded for intraocular surgery. There has, as a result, been a rush to purchase YAG lasers, and surgeons who have busy practices may acquire them in their private offices.

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[1] Excerpted from a paper prepared for OTA by Safir (267).

Table 16.—U.S. and Foreign Medical Devices Patents Granted by U.S. Patent Office by Application Date, 1968-79

	Number			Annual percentage change		
Year	Total	United States	Foreign	Total	United States	Foreign
1979[a]	2,142	1,488	654	5.3%	2.0%	13.5%
1978[a]	2,035	1,459	576	-4.8	-7.0	1.4
1977	2,137	1,569	568	3.8	1.6	10.7
1976	2,058	1,545	513	3.2	0.1	13.7
1975	1,994	1,543	451	-0.5	1.8	-5.8
1974	1,995	1,516	479	6.6	4.0	15.7
1973	1,871	1,457	414	9.4	8.1	14.0
1972	1,711	1,348	363	4.0	-1.0	28.3
1971	1,645	1,362	283	6.1	8.2	-2.7
1970	1,550	1,259	291	9.1	9.2	8.6
1969	1,421	1,153	268	12.7	9.9	26.4
1968	1,261	1,049	212	—	—	—
Total	21,820	16,748	5,072			

[a] The average pendency (i.e., the delay between the filing of a patent application and its subsequent issuance as a patent) is currently longer than 2 years. It is estimated that 2 to 5 percent of the 1979 applications and 1 percent of the 1978 applications were still pending in June 1983.

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, Rockville, MD, compilation of unpublished data from the U.S. Patent and Trademark Office, December 1983.

Table 17.—U.S. and Foreign Medical Devices Patents Granted by U.S. Patent Office by Source and Selected Categories, 1968-79

Category	Total number of U.S. and foreign patents[a]	Percentage of total[b]			
		Corporations	U.S. Government	Universities	Individuals
Diagnostic equipment	3,037	56%	4%	3%	37%
Respiratory methods	1,042	55	2	c	43
Electrical systems	723	68	1	2	29
Implantable artificial body members	1,236	48	4	4	44
Dialysis and blood filters	440	68	4	2	26
Kinesitherapy equipment	1,015	32	1	1	66
Orthopedic devices	590	21	1	1	76
Bandages and trusses	1,880	46	1	1	52
Medicators	2,502	61	1	1	37
Instruments	2,290	49	1	1	49
Dental equipment	1,509	33	c	1	66
Ophthalmic equipment	1,110	59	1	1	39
Miscellaneous, including incubators, hearing aids, receptors, and baths	2,525	58	2	1	39

[a] Includes patents granted (as of June 1983) on applications filed from 1968-79. The average pendency (i.e., the delay between the filing of a patent application and its subsequent issuance as a patent) is currently longer than 2 years. It is estimated that 2 to 5 percent of the 1979 applications and 1 percent of the 1978 applications were still pending in June 1983. One patent may be included in more than one category.

[b] Percentages may not add up to 100 percent because of rounding.

[c] Less than 1 percent.

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, compilation of unpublished data from the U.S. Patent and Trademark Office, December 1983.

electromedical, and electrotherapeutic equipment, SIC code 3693). Considerable activity also occurred in dialysis and blood filters, whose use has been covered by Medicare since 1972 (see ch. 3), and in diagnostic and implantable cardiovascular devices (see ch. 5).

Both large and small firms play a role in the innovation of medical devices, as they do in other sectors of the U.S. economy (274). There is no exact information, however, on the dynamic relationship between large and small medical device companies. It has been suggested that small firms introduce innovative devices and, after proving their commercial potential, merge or are acquired by larger, more stable companies (18). It is also possible that larger companies and establishments benefit from economies of scale, while the smaller ones specialize in products or functions that are not so dependent on scale (393).

INTERNATIONAL COMPETITIVENESS OF U.S. MEDICAL DEVICES

The United States has commanded a strong position in the foreign trade of medical devices. During the past decade, the surplus of U.S. medical devices exports over imports grew steadily until 1982. In 1983, the surplus fell from over $1 billion in 1982 to about $800 million (table 18). The $2.3 billion of medical devices exported in 1982 represented 17 percent of total sales (22,368). From 1978 to 1981, U.S. exports of medical devices grew about 19 percent a year, a substantial amount even though it does not allow for the 9 percent U.S. inflation rate at that time (219).[7]

U.S. foreign trade in medical devices contrasts with U.S. total merchandise trade, which has run a deficit (imports exceeded exports) for all but 2 years (1975 and 1976) since 1973 (358). The U.S.

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[7] See app. H on consensus standards related to international trade and app. I on governmental regulation of foreign trade in medical devices by six countries.

Table 18.—U.S. Exports and Imports of Medical Devices by SIC Code, 1979-83

SIC code	Millions of dollars					Percent change
	1979	1980	1981	1982	1983[a]	1982–83
X-ray and electromedical equipment (SIC 3693)						
Exports	$ 717	$ 839	$1,006	$1,026	$1,065	3.8%
Imports	275	312	388	487	670	37.6
Surplus (deficit)	442	527	618	539	395	—
Surgical and medical instruments (SIC 3841)						
Exports	410	485	566	605	585	-3.3
Imports	146	174	195	222	255	14.9
Surplus (deficit)	264	311	371	383	330	—
Surgical appliances and supplies (SIC 3842)						
Exports	258	309	356	375	395	5.3
Imports	105	94	95	108	110	1.9
Surplus (deficit)	153	215	261	267	285	—
Dental equipment and supplies (SIC 3843)						
Exports	101	127	140	143	155	8.4
Imports	42	41	50	50	55	10.0
Surplus (deficit)	59	86	90	93	100	—
Ophthalmic goods (SIC 3851)						
Exports	99	114	123	113	110	-2.7
Imports	245	278	300	342	452	32.2
Surplus (deficit)	(146)	(164)	(177)	(299)	(342)	—
Total, five SIC sectors						
Exports	$1,585	$1,874	$2,191	$2,262	$2,310	2.1%
Imports	$ 813	$ 899	$1,028	$1,209	$1,542	27.5%
Surplus (deficit)	$ 772	$ 975	$1,163	$1,053	$ 768	—

[a] Estimated.

SOURCES: W.C. Bandy, U.S. Department of Commerce, Bureau of Industrial Economics, Washington, DC, personal communication, January 1983; E. Arakaki, U.S. Department of Commerce, Washington, DC, personal communication, February 1984; U.S. Department of Commerce, Bureau of Industrial Economics, *1984 U.S. Industrial Outlook*, Washington, DC, January 1984.

position in medical devices is especially noteworthy because the growing strength of the dollar during the last decade increased the relative price of U.S. exports as it decreased the price of U.S. imports. That phenomenon did erode the U.S. surplus in 1983. The surplus in medical devices trade has also persisted during the recent recession, despite the reduced buying power of our major trading partners.

In 1983, the European Economic Community was the outlet for 37 percent of U.S. exports of medical devices, but Canada (14 percent) and Japan (10 percent) were the major individual purchasers.[8] The European Economic Community also provided more than half of U.S. imports, with West Germany (32 percent) and Japan (18 percent) the largest single sources (369).

Although U.S. production is greater in other categories of medical devices, SIC 3693 (X-ray and electromedical equipment) leads exports, with $1 billion or almost 50 percent of all U.S. foreign sales of medical devices. Domestic production in this category is heavily tied to export: 30 percent of electromedical equipment and 24 percent of X-ray equipment in 1983 were sold overseas (369). As a result, sales of these devices are more dependent on fluctuations in exchange rates.

Electromedical equipment, with exports that grew almost 25 percent annually from 1978 to 1981, accounts for most of the trade surplus in SIC 3693 (219). Although it is common that the U.S. share of the world market for a product declines over time as other countries enter the field and U.S. growth falls behind a faster growing world market, this situation has not occurred with electromedical equipment. The U.S. share of the world market increased from 35 percent in 1975 to 47 percent in 1979 (219). Patient monitoring systems and other diagnostic electromedical apparatus have accounted for the majority of these exports (371,372). In 1981, Japan, Canada, the Netherlands, West Germany, and France purchased almost half of U.S. exports in this subcategory.

Trade in X-ray products has been less favorable. In 1982, exports only slightly exceeded imports. A deficit of $175 million was expected for 1983, with imports accounting for 33 percent of U.S. consumption of all X-ray products (369). About 40 percent of all X-ray products imported during 1981 and 1982 were X-ray apparatus and parts from West Germany (373,374).

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[8] These figures relate to SIC codes 3841, 3842, 3843, and 3693 but exclude SIC code 3851 (ophthalmic goods).

Although SIC 3841 (surgical and medical instruments) showed a trade surplus in 1983, its position deteriorated from 1982: exports fell 3 percent and imports grew 15 percent. About 15 percent of the surgical and medical instruments produced in the United States during 1983 were exported, but only 7 percent of U.S. consumption came from imports. Exports of surgical and medical instruments indicate the untapped potential of markets other than our traditional trading partners. From 1978 to 1981, exports to Canada (17 percent) and the European Economic Community grew about 12 percent per annum. Exports to the Middle East (10 percent) and Latin America (18 percent), however, grew nearly 30 percent per annum (219,371).

SIC 3842 (surgical appliances and supplies), the largest medical devices category in sales, has the least relative involvement in foreign trade: only 7 percent of production is exported, and 2 percent of U.S. consumption is imported (369). From 1982 to 1983, exports experienced a 5-percent increase, and imports rose almost 2 percent. Both West Germany and Japan had sizable increases in their exports to the United States.

Exports of devices in SIC 3843 (dental equipment and supplies), representing 12 percent of production, increased 8 percent from 1982 to 1983. Imports, only about 5 percent of U.S. consumption, came mainly from West Germany and Japan (369).

SIC 3851 (ophthalmic goods) is the only medical devices code that has had a persistent trade deficit. Half of the imports consist of frames and mountings for eyeglasses, which are supplied primarily by France, Italy, Japan, and Hong Kong. Sunglasses, 38 percent of ophthalmic imports in 1981, came mainly from Japan and Hong Kong (373). Unlike most products in the other medical devices codes, ophthalmic goods are usually chosen and used by consumers rather than by medical providers. To the extent that use is discretionary or postponable, sales would be expected to be more sensitive to changes in price and general economic conditions. That reduced exports in sunglasses accounted for most of the fall in exports from 1981 to 1982 fits this pattern.

CONCLUSIONS

The medical devices industry can be characterized as a field that has undergone enormous growth in companies, establishments, employment, new products, and foreign trade. By all of these measures, the experience of the medical devices industry has exceeded that of manufacturing as a whole and of similar manufacturing sectors. Growth in medical devices has apparently occurred more by the addition of new companies than by the expansion of old ones, an indication that any barriers to entering the industry are not prohibitive. Both small and large firms have important positions in this industry. Small companies are responsible for a greater percentage of sales in the medical devices industry than in other industries. But large companies have accounted for the majority of sales, and a small number of firms have a considerable share of the market, especially in specific product lines.

There are, however, disquieting aspects to the situation. This phenomenal growth has occurred in a market where there is a consensus that technology, including medical devices, has sometimes been used excessively (168,266,346). Policy initiatives, both public and private, are now under way to improve the situation, chiefly by changing the way that medical providers are paid. In addition, Federal policy regarding premarket approval of devices is under review. It is therefore timely to analyze the likely effects on the medical devices industry of these and other policies, a task that is undertaken in the remainder of this report.

3.

Payment Policies for Health Care and Medical Devices

We prefer to blame technology rather than our cultural institutions for the great cost overrun of the American health care system

—*Dale R. Olseth*

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3.

Payment Policies for Health Care and Medical Devices

INTRODUCTION

The market for health care services is more complicated than most other sectors of the economy. The ultimate consumers of health care typically do not pay for services at the time they are rendered; third-party payers—insurance companies, Medicare, Medicaid, and other Government programs—share in the cost of providing medical services to their beneficiaries. Only about 32 percent of total personal health care expenditures are paid directly by patients (128).

The market for health care services is also complicated by the central role of the provider—the physician, other health professional, or hospital—in making decisions about the amount, kind, and quality of services that the patient receives. Most diagnostic and therapeutic medical procedures, prostheses, and implants must be ordered by the physician. Thus, the makers of medical devices more frequently see the provider as the buyer than they do the patient or consumer.[1]

Manufacturers of medical devices, like those of other products, try to produce and price products to meet the demands of their market. If low price is important to buyers, then, barring the existence of monopoly power,[2] the producers will attempt to make products that can sell profitably at low prices. If price is not so important to customers, producers will focus on factors that are. Since the system of third-party payment for health care services influences the products that will be bought and the prices that will be paid, it is a major determinant of the market for medical devices.

Payment issues also influence the long-run performance of the industry. In general, the success or failure of a technological innovation rests partly on developers' perceptions of its market (201,232,264). Although technological opportunities may dictate what directions of advance are feasible, the perceived existence of a market for an innovation is necessary for the commitment of research and development (R&D) funds or the investment in commercialization. There is no evidence to suggest that the medical device industry is different from other industries in this regard.

Other factors besides the payment system shape markets for medical devices. Both the benefits and costs of medical devices matter. First, the buyers and users must perceive a device to be worthwhile. Devices that are unsafe, ineffective, or less effective than their substitutes may not have a market even in the presence of generous third-party payment. Gastric freezing is an example of a device-bound procedure that was abandoned soon after evidence accumulated that it did not help ulcer victims, in spite of the willingness of third-party payers to finance its use (114). However, many devices have been widely used even though well-documented evidence of their effectiveness is lacking.

Second, the availability of an important new device whose cost, configuration, or setting of use currently limits or proscribes third-party payment can stimulate a change in payment policy. The case of long-term hemodialysis therapy for end-stage renal disease is a classic example (256). With the development of a subcutaneous arteriovenous shunt (a plastic tube connected to an artery and a vein in the arm or leg) by Quinton and Scribner in 1960, hemodialysis rapidly became accepted as a life-extending therapy for victims of chronic kidney failure.

In 1972, Congress extended Medicare coverage for treatment of end-stage renal disease to the gen-

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[1] An important and growing class of devices are those made expressly for use in the home or by the consumer. These include self-care products such as self-testing diagnostic kits and aids for handicapped people that are often marketed directly to the consumer.

[2] This assumption is important in gauging the response of the industry to the preferences of consumers.

Photo credit: National Kidney Foundation, Washington, DC

This man is undergoing hemodialysis for the treatment of end-stage renal disease (ESRD). Medicare began paying for such treatment in 1973, and by 1982, expenditures for Medicare's ESRD program were an estimated $1.8 billion.

eral population (Public Law 92-603), largely out of a recognition that there occurred an estimated 7,000 to 10,000 deaths per year because of the limited availability of dialysis facilities (256). This program now pays $1.8 billion annually for hemodialysis for approximately 80,000 people (98).

Third, many new medical devices are perceived to have such benefit that they are demanded whether or not they are covered by insurers. In dentistry, for example, many new materials have been developed in the recent past (184,210), despite the fact that almost 70 percent of dental expenditures are paid directly by patients (128).

With the recognition that other factors affect the markets for medical devices, this chapter describes how third-party payment, particularly Federal payment programs, affects the kinds of medical devices that are produced, the settings in which they are used, and the prices at which they sell.

Medicare and Medicaid, the two Government health insurance programs, are responsible for about 35 percent of payments for personal health care made to hospitals, 23 percent of those to physicians, and 23 percent of all other medical expenditures (128). Private health insurance, including commercial (for-profit) insurance companies and (not-for-profit) Blue Cross/Blue Shield plans, accounts for another 33 percent of hospital and 35 percent of physician expenditures. Other Federal, State, and local government programs also contribute 13 percent of personal health expenditures through the Veterans Administration (VA), the military medical system and its related Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) program, and Government owned and operated health facilities (128).

If all sources of third-party payment and Government funding are taken together, the individual consumer or patient bears a moderate proportion of the burden of personal health care expenditures in this country (32 percent). But the distribution varies widely by settings and types of technology. Patients pay only about 12 percent of hospital expenditures directly, but they pay 37 percent of payments to physicians and almost 77 percent of expenditures for eyeglasses and appliances (128). The burden of payment also varies widely in the population. Some people have comprehensive health insurance, although an estimated 32.7 million people under age 65—or about 16 percent of the population under age 65—were without any public or private insurance coverage in 1982 (295a).[3]

Three aspects of third-party payment can influence the potential market for medical devices:

- the coverage of devices as benefits by third-party payers;
- the methods used to determine the level of payment for covered health services; and
- the financial relationship between the payer and the provider of health care.

Each of these elements is discussed in the sections below.

THIRD-PARTY COVERAGE OF MEDICAL DEVICES

Economic theory predicts and empirical evidence confirms that the existence of insurance coverage for a technology increases the number of such services used (29,233,279). It has also been shown that the use of physician and hospital services varies inversely with the amount of cost-sharing required of the consumer (233). Not only have people sought care less often under cost-sharing, but their total annual health expenditures have been lower than for people without cost-sharing requirements. Insurance coverage also affects the adoption of new medical technologies. In two studies, a positive relationship was found between the proportion of a State's population with health insurance and the adoption of complex and sophisticated facilities in hospitals (71,266).

Most health insurance plans are selective in their definition of covered technologies. Insurers avoid certain services whose use may be difficult to predict or control. For example, mental health services are frequently excluded from both public and private insurance policies, as are some long-term care and home health services (55). The Medicare program covers inpatient hospital care more fully than other services but requires some cost-sharing by beneficiaries and limits the number of hospital days covered.[4] Physician services and ambulatory laboratory services are covered, but annual deductibles and copayments are required of beneficiaries. Other services, such as outpatient drugs, eyeglasses, hearing aids, and preventive services are either uncovered or covered to a very limited extent under Medicare (345).

Coverage decisions are often more complicated than the all-or-nothing decision about general classes of services. By statute, Medicare may pay only for services that are "reasonable and necessary" for diagnosis, treatment, or improved functioning of a malformed body member. Medicare has refrained from establishing a definitive interpretation of reasonable and necessary and has relied on a loosely structured and decentralized mechanism to determine whether a specific service is covered. Under the present Medicare program, funds are passed from the Federal Government to many separate contractors (referred to as intermediaries and carriers) who reimburse providers or consumers for the services delivered in their area.[5]

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[3] The uncovered population increased dramatically between 1979 and 1982. In 1979, 14.4 percent of those under 65 years of age were uncovered, and in 1982, 18.9 percent of those under 65 were uncovered. Economic conditions in the period and increases in the costs of health insurance relative to other goods and services are responsible for these changes (295,296).

[4] Medicare consists of two separate but coordinated programs—Hospital Insurance (Part A), and Supplementary Medical Insurance (Part B). Under Part A, beneficiaries receive up to 60 full days of hospital care per year after a deductible is satisfied. Part B, which is voluntary and requires a premium, has both a deductible and a beneficiary payment of 20-percent coinsurance.

The contractors are responsible for implementing Medicare coverage policy. Decisions involving coverage of services, particularly new services, are often made on a case-by-case basis and thus may vary from region to region. For example, prosthetic devices may be covered under Medicare if they replace all or part of an internal body organ or replace the functioning of a permanently inoperative or malfunctioning organ. But communications aids, considered by numerous health professionals to be prosthetic devices, are not specifically covered under Medicare. Coverage is largely at the discretion of the contractor (345).

A rather informal system exists for referral of coverage issues that cannot be resolved by the contractor to Medicare's regional office and, if necessary, to the Federal Health Care Financing Administration (HCFA), which often turns to the Office of Health Technology Assessment[6] in the Public Health Service for guidance. There is apparently some chance involved in which issues get flagged for referral (343).

Medicare contractors vary widely in their identification of uncovered technologies, the decisions they make concerning the coverage of specific technologies, and their implementation of coverage decisions (51,79,343). In short, coverage of some services, particularly new procedures, under Medicare is variable and uncertain. Such uncertainty may reduce in the eyes of the developer the expected monetary return from introducing a new medical device whose coverage is questionable. Increasingly, the manufacturers of new devices have themselves approached HCFA for definitive guidance on coverage (345), perhaps in an attempt to reduce the interregional variation and uncertainty associated with the coverage process.

In general, third-party payers will not cover a new device until it is approved for marketing by the Food and Drug Administration (FDA) (see ch. 5). For example, Medicare will cover no drug or device that is in the investigational category. It is interesting to note, however, that the Medical Device Amendments of 1976 (Public Law 94-295) do not prohibit the manufacturers of an investigational device from selling their product to users. The producer may charge a price for an investigational device that will recoup research, development, and production costs but may not make a profit.

Although the buyers (health care providers) generally cannot charge third-party payers directly for an investigational device, they can sometimes charge for it through other, similar, procedures that are already covered.[7] In the words of one legal expert, "investigational devices pay their own way" (84). This expert also noted that large and small device-makers charge institutions, practitioners, and patients for devices that are available only under an FDA investigational device exemption (IDE).

Some investigational devices have become widely diffused in the absence of either premarket approval or specific coverage by the major third-party payers. As an example of FDA's policy of limiting distribution of devices under IDE, the agency recently issued a "guidance" letter to nine manufacturers of yttrium aluminum garnet (YAG) lasers (used in ophthalmology) limiting investigational uses to 500 patients in a 6-month period because it was concerned that the widespread distribution of these devices still in the investigation stage constituted commercialization (88).

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[5] Coverage is important for new devices where payments are made for each service delivered as in a fee-for-service system. In Medicare, coverage affects the services of physicians and other health professionals more than hospitals, because they are paid on a fee-for-service basis whereas hospitals are paid by the admission.

[6] The Office of Health Technology Assessment (OHTA) in the Department of Health and Human Services is the office in the Public Health Service that is charged with advising HCFA on Medicare coverage of specific technologies. OHTA is distinct from the Office of Technology Assessment (OTA), a staff agency of Congress that performs studies requested by congressional committees and has a Health Program.

[7] If the device is part of a research program, a research grant may pay for its use.

Limitations on and exclusions from coverage increase the difference between the out-of-pocket price of covered and uncovered services. When covered and uncovered services compete as substitutes for one another, the uncovered services are at a distinct disadvantage. To have a chance of being used, the uncovered service would have to offer patient benefits sufficiently greater to justify the higher out-of-pocket expense. The effect of differential coverage levels on the market for a medical device depends, of course, on whether the device is covered by most insurance plans, which patient conditions are covered for payment, whether substitutes for the device exist—and if substitutes exist, whether these alternative services are covered under insurance policies as well.

The effects of a coverage decision on medical devices vary with the specific characteristics and conditions of use of devices. For example, a new cataract removal procedure made possible by a new device may lower the cost to the physician of performing the procedure. The physician can introduce the cost-saving method and bill the patient or insurer for the standard cataract removal procedure (at fees that are not likely to reflect the reduced costs).[8] Thus, to the extent that new techniques or devices can be subsumed under existing medical procedure categories, coverage is not of great concern. However, if the cost of the new approach is higher than the level of payment for existing procedures, coverage becomes an important milestone in the development of a viable market for the technique. Using old procedure codes for the new technique will not be attractive to physicians.

Although the introduction of some new medical devices may be discouraged by the practical obstacles to third-party coverage, there is no ongoing mechanism in Medicare to reverse coverage decisions when an existing device has been found to be less effective than other approaches. For example, Medicare has continued to cover intermittent positive pressure breathing (IPPB), a mechanical ventilator for respiratory therapy (246,272), despite the fact that several professional societies have seriously questioned its value.

The history of IPPB also illustrates the important role of professional judgment in influencing the use of a procedure. Despite the coverage by third parties, the use of IPPB has decreased dramatically in the past decade (see box C) (20,43, 49,248,272).

Thus, it appears that the process by which devices come to be covered (or removed from coverage) by third-party payers is idiosyncratic. Under Medicare, some devices are "grandfathered" into coverage by virtue of their age; some are covered by default because they can be paid within preexisting medical procedure codes. Others are denied coverage, or given very limited coverage for a period of time. The degree of ease with which a particular device receives the blessing of coverage from the major third-party payers appears to have little to do with the device's relative efficacy or cost effectiveness (24) and more to do with the accident of timing of its introduction to medical practice.

METHODS OF THIRD-PARTY PAYMENT AND THE DEMAND FOR MEDICAL DEVICES

Insurers use a variety of mechanisms to pay for covered services provided to their beneficiaries. In the simplest case, the insurer makes fixed indemnity payments to the beneficiary, who is responsible for paying the provider whatever is charged. Other plans pay for the full costs of services to the beneficiary (less any deductibles and coinsurance) up to a schedule of maximum allowances.

Medicare, Medicaid, and many Blue Cross/ Blue Shield plans enter into contracts with "par-

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[8] See the section below on "Payment for Physicians devices" for an explanation of this phenomenon.

Box C.—Intermittent Positive Pressure Breathing (IPPB)

IPPB devices are mechanical ventilators which, once triggered by the beginning of the patient's inspiration, deliver a single "breath" of air. Such devices can be adjusted for sensitivity so that even very weak patients can trigger the machine with every attempted breath. The patient usually uses only a mouthpiece, although a face mask can also be used (467).

The four basic functions of IPPB devices are: 1) to inflate the lungs fully; 2) to deliver any specified mixture of gases (including room air) to the lungs; 3) to deliver aerosols (either bland, to moisten the lung, or medicinal): and 4) to stabilize breathing. Common alternative respiratory therapy devices include blow bottles and incentive spirometers, which help inflate the lungs, and nebulizers, which deliver aerosols. IMS data show that sales of IPPB devices have decreased by about one-third in the past 5 years, while sales of nebulizers, for example, have doubled in the same period (166). Professional-journal articles have also reported that use of IPPB devices has decreased since the early 1970s (20,43,248,272).

Reasons for the decrease in IPPB sales and use are not related to payment policies. Rather, the medical profession began in the early 1970s to scrutinize criteria for respiratory therapy in general and the administration of IPPB therapy in particular (266,287).

IPPB emerged out of World War II efforts to provide adequate ventilation for high-altitude pilots. A landmark paper by Motley and his colleagues in 1947 (221) introduced the clinical use of IPPB to the medical profession. The 1950s and 1960s saw the gradual diffusion of IPPB technology into hospitals and homes (58,459). Criticisms of indiscriminate use were published, but use increased dramatically nonetheless (25).

With the adoption of Medicare and Medicaid legislation in 1965, the public endorsed IPPB use. No conscious decision to cover this procedure was ever made; the technology was in widespread use at the time of passage. Blue Cross/Blue Shield plans also covered treatments without question.

IPPB therapy was common long before any rigorous tests of its efficacy were made. The clinical studies reported in the literature during its diffusion tended to use methods that were poorly designed or difficult to duplicate (272). The lack of good clinical data exacerbated the controversy over its proper use.

In the 1970s, several professional groups began to strongly question the use of IPPB devices. A 1974 National Heart and Lung Institute conference on the scientific basis of respiratory therapy concluded that the literature on IPPB warranted closer examination of the technology, especially through controlled clinical trials. By the time of the National Heart, Lung, and Blood Institute (NHLBI) conference in 1979, respiratory therapy textbooks were beginning to emphasize more stringent criteria for IPPB use (467), and the American Association of Respiratory Therapists (AART) had endorsed guidelines for use prepared by the American Thoracic Society (4).

Shortly after the 1979 conference, an OTA-contracted case study circulated a critical appraisal of IPPB to a slightly different audience (272). With this report to give it credibility, the Blue Cross/Blue Shield Association began an assessment of IPPB use and insurance coverage, in cooperation with the American College of Physicians and other professional groups (36).

While public awareness of the potential for IPPB overuse has risen, the controversy in the medical profession has slowed considerably. "Consensus papers" such as the AART and Blue Cross/Blue Shield guidelines still may find strong opposition on some points (278), but there has been little hard argument carried in medical journals in the past few years. A 1981 NHLBI Task Force on Pulmonary Technology did not even mention IPPB (402).

ticipating" providers that specify the methods for determining the level of payment that providers will receive. Because of the importance of Medicare, Medicaid, and the Blue Cross/Blue Shield plans as sources of revenue, these methods of payment are critical determinants of the market for medical devices.

Methods of payment vary widely across insurers and settings of care. This section will focus on current and proposed methods of paying for inpatient hospital care, physicians' services, laboratory tests provided in ambulatory care settings, and services or devices used in the home. These four components constitute over 80 percent of health expenditures and make intensive use of medical devices.

Hospital Payment

Public and private third-party payers were responsible in 1980 for over 83 percent of the revenues of community hospitals in the United States (108). Private health insurance itself accounts for 38 percent, while Medicare and Medicaid comprise 42 percent. Individual patients are the source of about 17 percent of the revenues of community hospitals.

Third-party payment for hospital care has traditionally taken two forms: payment of billed charges and payment of incurred costs. Most commercial insurance plans and about one-third of the 70 Blue Cross plans pay hospitals their billed charges.[9] In 1981, over one-half of the State Medicaid programs and about one-half of the Blue Cross plans reimbursed hospitals for the "reasonable costs" incurred in serving their beneficiaries (6,345). Medicare is in the process of abandoning this method of payment and moving to a new system, discussed later in this chapter. Both of these payment methods (by charges and costs) pass the immediate burden of payment through the patient to the third-party payer.

Charge- and cost-based third-party payments encourage increases in health care expenditures, because hospitals have no incentive to hold costs down.[10] Only to the extent that patients themselves react to costs (or charges) by taking their business elsewhere (if they can) will the hospital have an incentive to compete for patients in terms of price. Since patients themselves pay so little out-of-pocket for inpatient care, they have little incentive to concern themselves with price. The predominance of third-party cost- and charge-based payment has been held responsible for the rapid increase in hospital expenditures (110).

The problem of growing hospital expenditure inflation increased during the 1970s and led both public and private third-party payers to modify payment methods. A number of Blue Cross plans, individual States, and now the Federal Government have turned to prospective payment.[11] Although prospective payment methods vary widely among States and payers, they have two features in common: the amount that a hospital is paid for services is set prior to the delivery of those services, and the hospital is at least partially at risk for losses or stands to gain from surpluses that accrue during the payment period.

Evidence has accumulated that in recent years some State-level prospective payment programs, particularly those with relatively stringent systems, have had a moderating influence on hospital costs (33,60). What have these reductions in hospital costs implied for the adoption of medical technology? Three studies of the impact of hospital prospective payment programs on the adoption of new capital equipment or equipment-embodied services suggest that prospective payment sometimes does affect technology adoption and that the directions of effect depend on both the specific attributes of the programs and the characteristics of the new technology.

Joskow found that the number of computed tomography (CT) scanners located in hospitals in a State in 1980 was negatively related to the number of years that ratesetting had been in effect there (177). Hospital ratesetting also led to a shift in the location of CT scanners to physicians' offices. Cromwell and Kanak analyzed the impact of specific State ratesetting programs on the availability of 13 different services in the hospital between 1969 and 1978 (72). Two States with stringent programs, New York and New Jersey, had the most consistently negative effects on the availability of services. Other States' programs showed no consistent impact on service adoption.

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[9] A small percentage of commercial policies are indemnity plans, where the insurer pays the patient a fixed amount, such as $100 per day of hospitalization. Only about 10 percent of group policies written by commercial insurance companies are indemnity plans (456).

[10] Such incentives apply when costs of production are reimbursed, as under Medicare, but differ when payments are below costs as under some Medicaid programs (138).

[11] Prospective payment has also been called prospective reimbursement.

Finally, Wagner and colleagues investigated the impact of prospective payment in three States—New York, Maryland, and Indiana—on the adoption of five new pieces of capital equipment: electronic fetal monitoring, gastroendoscopy, volumetric infusion pumps, automated bacterial susceptibility testing, and computerized energy management systems (448). The first three technologies are likely to raise the cost of care, while the latter two are investments in equipment that is cost-reducing in large hospitals. Under New York State's ratesetting program, fewer units of the cost-raising technologies were adopted, and the probability of large hospitals' adopting the cost-saving equipment increased. However, the prospective payment programs in Maryland and Indiana showed no such consistent effects on hospitals' adoption behavior.

Medicare's DRG Hospital Payment System

In March 1983, Congress established a new Medicare hospital prospective payment system (Public Law 98-21). Beginning in October 1983, Medicare began to phase in a system in which it will pay hospitals a fixed price for treating each admission in 470 separate diagnosis related groups (DRGs) of patients. At this time, the price paid for each admission in a particular DRG covers hospital inpatient operating costs—leaving outpatient, teaching, and capital expenses reimbursed on a cost basis for the time being.

The new system is a Medicare-only approach, but the law allows Medicare to join State-run prospective plans to cover all kinds of payers. Support from private insurance companies and businesses for these systems is high. Thus, the Federal move into prospective payment may presage a more general adoption of this kind of payment by States.

Because Medicare accounts for such a large percentage of hospital revenues, the new per-case payment system should put into place strong incentives for hospitals to change their behavior regarding the adoption and use of medical devices, as well as all other inputs, because hospitals will be able to retain any surplus and must bear all deficits. One can expect the adoption of some devices, particularly those that reduce the cost per hospital stay, to be encouraged, relative to their past experience. Compared to practice in the recent past, the adoption of cost-raising devices will be discouraged, but the strength of that effect will depend on the device. Some may be less affected if hospitals compete for admissions by adopting new device-embodied services, while others that do not affect the competitive position of hospitals are likely to face a more hostile adoption environment (see box D for more detail).

The new Medicare payment system should also alter the settings in which services are delivered to Medicare patients. In particular, the use of nursing homes and home health care should increase as hospitals seek to reduce the lengths of stay of Medicare patients. Moreover, payment for care delivered in these settings is not so constrained as that in the hospital. Devices that can be used in the home should find an increasing market.

Some observers are predicting, for example, that the already growing market for parenteral and enteral nutrition (techniques of direct feeding into the bloodstream or gut) in the home will be increased by DRG payment, and that hospitals will enter the market as providers of after-hospital home care in direct competition with other providers, some of whom are manufacturers of equipment and supplies for parenteral and enteral nutrition (34).

The law may also influence the pricing behavior of device manufacturers. As hospitals become more price-conscious with the advent of per-case payment, they are likely to increase their use of group purchasing, standardization of purchasing, and competitive bidding for equipment and supplies. Group purchasing as a phenomenon has grown rapidly among hospitals in the United States, with an estimated 88 percent of hospitals belonging to a purchasing group in 1981 (99), but

Box D.—DRG Hospital Payment: Predicted Effects on Selected Medical Devices[1]

Product category	*Typical products*	*Predicted effects*
Implants	Pacemakers, heart valves, artificial joints, orthopedic plants, intraocular lenses	For those high-cost implants that represent a large fraction of the DRG rate, increased focus on product selection, with unit cost important.
Chemical laboratory equipment and supplies	Clinical chemistry, hematology and radioimmunoassay instruments; microbiology systems	Increased hospital demand for cost-reducing, highly productive laboratory instruments. Downward price pressures and efforts to control inventories in laboratory supplies. New tests leading to early diagnosis and shorter stays accepted readily. Shift of some testing (e.g., preadmission) outside hospitals.
Patient monitoring equipment	Intensive care unit (ICU) monitoring systems, electronic fetal monitors, blood gas monitors, monitoring electrodes and supplies	Hospital under heavy pressures to limit access to monitoring services wherever benefit is questionable. Hardware innovations carefully evaluated for utility and cost effectiveness. Demand for longer lasting, labor-saving, more reliable new products. Market may shift to larger hospitals.
Respiratory therapy products	Breathing circuits, intermittent positive pressure breathing (IPPB) apparatus, nebulizers, ventilators, oxygen delivery systems, associated supplies	Use of these products may be reduced whenever there is no clear-cut and obvious need. Careful scrutiny of all replacement decisions; less interest in marginal improvements.
Diagnostic imaging and therapy systems	X-ray, ultrasound, computed tomography, nuclear imaging, angiography, film, cassettes, supplies	Demand will remain high because of measured utility and relatively noninvasive nature. Price competition in supplies likely to increase and overall market for supplies will shrink as utilization is curtailed.
Bedside services and disposables	Disposable bedpans, washbasins, toiletries	Two opposing incentives: increased admissions will increase demand; pressure to reduce cost leads to more careful hospital purchasing and closer evaluation of routine distribution of these products.

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[1] Based on the Health Industry Manufacturers Association's Prospective Payment Fact Book as discussed in *Medical Device and Diagnostic Industry*, "The Effect of DRGs on Devices and Diagnostics," vol. 6, No. 2, pp. 31-36, February 1984 (211).

it is still largely confined to drugs and hospital supplies as opposed to equipment.

There is some evidence that the VA has been able to exact significant price concessions from manufacturers through its competitive contract purchasing system (see ch. 7). A recent survey of 25 hospitals in 10 States by the Inspector General of the Department of Health and Human Services (DHHS) found that the price of cardiac pacemakers for Medicare patients was about 17 percent higher than the price paid by the VA (427).

As hospitals face increasing pressure to reduce the costs per admission under the new payment system, standardization of purchasing behavior is likely to occur, reducing the range of choice open to physicians and allowing hospitals to reap the benefits of increased market power. The expected result in any particular device category is narrower price ranges and less variation among products.

An unresolved issue with important implications for medical devices is how Medicare will pay for hospitals' investments in capital plant and equipment in the future. For the present, the method of payment for capital costs (depreciation, interest, and return-on-equity to for-profit institutions) has not been changed. Capital expenditures are reimbursed as they are incurred, on a cost basis. Congress has expressed an intention to include payment for capital by 1986 as part of the prospective payment rate, but no specific method has been selected.

The present cost-based method of capital payment is inefficient because hospitals have little incentive to weigh the costs and benefits of purchases and hence are likely to adopt and use medical equipment regardless of the cost effectiveness. Table 19 indicates how hospitals' incentives to adopt different kinds of capital equipment under DRG payment are influenced by a passthrough of capital (payment of the capital costs that are incurred).

The capital payment method does not reverse incentives of DRG payment so long as the effect on total hospital costs of a medical equipment purchase is in the same direction as its effect on operating costs. For example, DRG payment provides a disincentive to adopt most cost-raising, quality-enhancing (Type I) capital equipment. Regardless of the way capital costs are handled, such purchase would raise operating costs. The capital passthrough weakens the disincentive to adopt this kind of technology, but it does not remove it. Since DRG payment sets up incentives for hospitals to increase admissions, they have a financial interest to seek cost-raising equipment whose availability promises to bring in profitable admissions by attracting physicians and patients. A capital cost passthrough essentially subsidizes this kind of investment, leading potentially to wasteful duplication of these services among hospitals.

With equipment that saves operating costs (Type II) or capital costs (Type III), there can be situations where the policy regarding payment for capital may actually reverse the incentives of DRG payment regarding adoption. Of particular concern is the incentive under a capital passthrough to adopt expensive capital equipment that reduces operating costs but raises total cost per case. For example, with a capital passthrough, automated laboratory equipment might be evaluated in terms of its ability to reduce operating costs, with inadequate regard for its impact on total costs. And a more labor-saving capital-intensive system might be preferred regardless of its impact on net costs.

New, inexpensive equipment that replaces older, more costly equipment but only at the expense of increasing operating costs (Type III) will also be discouraged in a DRG system with a capital cost passthrough even if its adoption would decrease total costs (Type III-B). Over time, then, hospitals can be expected to become more capital-intensive than efficiency would dictate if the capital passthrough is continued.

Table 19.—Impact of Medical Equipment on Per-Case Hospital Costs

	Direction of effect of equipment purchase on:			Incentives for adoption	
Type of equipment	Capital cost per case	Operating cost per case	Total cost per case	With capital in DRG rate	Without capital in DRG rate
I. Cost-raising, quality-enhancing equipment	+	+	+	–	–
II. Operating cost-saving equipment					
A. Raises total costs	+	–	+	–	+
B. Saves total costs	+	–	–	+	+
III. Capital cost-saving equipment					
A. Raises total costs	–	+	+	–	–
B. Saves total costs	–	+	–	+	–

SOURCE: Office of Technology Assessment.

Payment for Physicians' Services

As the primary gatekeeper for the use of medical procedures, the physician is a key actor in decisions bearing on the adoption and use of medical devices. Most diagnostic and therapeutic services must be ordered by a physician or provided under a physician's direction. Although the patient always has the right to refuse services and can refrain from seeking care in the first place, this course is restricted by consumers' limited knowledge and a medical care system that exhorts that patient to "follow doctor's orders." The key role of the physician is reinforced by extensive insurance coverage, which reduces the patient's economic incentive to refuse or question services (139).

In 1982, physicians received approximately 37 percent of their revenues directly from patients, 35 percent from private insurance, 18 percent from Medicare, almost 5 percent from Medicaid, and the remainder from private philanthropy and other sources of Government support (128).

Third-party payers generally pay for covered physicians' services on a fee-for-service basis. There are two primary approaches to determining levels of payment: the benefit schedule and the fee screen (285). Under the benefit schedule approach, the insurer pays the patient or physician a predetermined fixed amount for each covered service. In private insurance plans, the patient is responsible for paying the difference between the physician's fee and the amount of the benefit, as well as any deductibles and coinsurance.

The fee-screen approach, used by Blue Shield plans, Medicare, and some Medicaid programs and commercial major medical plans, pays the physician's actual charge (less coinsurance and deductibles) up to some maximum amount that is computed from profiles of the physician's own fees and those of other physicians in the same specialty and region. This fee-screen approach is generally referred to as the usual, customary, and reasonable (UCR) approach to payment. Medicare uses a variant of the UCR system called customary, prevailing, and reasonable (CPR). Here, the CPR will refer to the general system of computing a payment rate based on historical and comparative profiles of physicians' fees.

Under its CPR system, Medicare pays 80 percent of the "reasonable charge": the lowest of the actual charge, the customary charge, or the prevailing charge for a service. The customary charge is the median charge for that service by the doctor, and the prevailing charge is the charge below which lies 75 percent of all charges for that service by doctors in a particular specialty and geographic area. Unless the physician enters into an agreement with the insurer to accept the CPR amount as payment in full (i.e., accepts assignment), which occurs in about 50 percent of all claims (113), the patient is responsible for paying the difference between the UCR rate and the physician's billed charge.

Beginning in 1976, increases in the Medicare prevailing charge have been restricted to a rate reflecting increases in personal income in the United States and the costs of medical practice. Over time, as physicians' actual fees meet or exceed the prevailing charge, Medicare's CPR system is becoming a de facto geographic- and specialty-specific benefit schedule. Thus, the difference between benefit schedules and CPR methods is rapidly becoming a moot point as far as the Medicare system is concerned.

The CPR system tends to put a premium on performance of new procedures for which comparative screens have not been established. A physician can charge a high fee for a new procedure and have it reviewed for its reasonableness by a medical review committee. After these fees are established and comparative screens are developed, the new procedure often remains highly rewarded relative to old procedures, because there is little financial incentive for physicians to lower prices as time goes on.

Thus, devices that allow for the performance of such new procedures should be highly valued by physicians, other things being equal. (Note, though, that new procedures may require a coverage decision, which may slow the adoption of such devices by physicians.) Gastroendoscopy is an example of a new device-embodied procedure that was introduced at high fee levels and that is today highly profitable to physicians who perform the procedure in sufficient volume (448).

New procedures are typically device-embodied, whereas the "thinking services" provided by physicians, even though they may embody advances in knowledge, are generally incorporated in existing procedure categories, such as the office visit. Hence, the bias toward higher rates of return to new procedures generally represents a bias toward device-embodied procedures relative to "cognitive services."

Schroeder and Showstack analyzed four illustrative styles of medical practice, ranging from infrequent to frequent use of laboratory tests that can be performed in the office (277). Physicians' net incomes increase as the intensity of laboratory procedure use increases. To deal with this problem, it has been suggested that uniform benefit or fee schedules should be constructed on a basis other than UCR, perhaps by experts reviewing data on the relative costs of procedures (137, 140). The effect of such a fee schedule on the use of device-specific procedures or the adoption of new ones would, of course, depend on the relative fees actually adopted. Should cognitive services be valued more highly relative to device-specific services, physicians would, other things being equal, have an incentive to spend relatively more of their patient-care time on them.

Payment for Ambulatory Clinical Laboratory Services[12]

Laboratory equipment, supplies, and reagents represent an important and rapidly advancing area of medical devices. Laboratory testing volumes have increased dramatically in the past decade, partly as a result of the development of new tests and automated equipment and partly as a result of third-party payment methods. Between 1972 and 1977, laboratory tests nearly doubled for both hospital and ambulatory care (126). Hospital laboratory test costs increased from $2.2 billion to over $4 billion, and out-of-hospital tests increased from 850 to 1,510 tests per 1,000 physician visits (126). During this same period, per capita visits to physicians decreased from 5.0 to 4.8 (126).

Payment for clinical laboratory services delivered to hospital inpatients is part of the hospital payment system described above. This section focuses on issues in payment for laboratory services rendered to ambulatory patients.

Laboratory tests are generally ordered by physicians and are commonly offered by three kinds of laboratories: those located in hospitals, those located in physicians' offices, and those independent of both hospitals and physicians' offices. In 1977, there were an estimated 7,200 hospital laboratories, 50,000 to 80,000 physicians' office laboratories, and an estimated 7,650 independent laboratories in the country (226,329,355).

The setting in which testing takes place is determined in part by the economics of laboratory testing. As new automated chemical laboratory technologies came to market in the 1960s, economies of scale in test production favored centralized testing in large independent laboratories, whereas more recently the development of simple new tests such as enzyme immunoassays and microprocessor-based equipment has favored decentralized testing in physicians' offices. But the methods of third-party payment also affect the profitability of testing in different settings and therefore influence the choice of testing location.

Medicare's methods of paying for ambulatory laboratory tests are particularly influential for three reasons: first, Medicare beneficiaries represent a substantial proportion of laboratory test use; second, in many States, Medicaid uses Medicare's payment methods to pay for ambulatory laboratory services; and third, physicians tend to make decisions on the location of testing for their practice as a whole, not on a specimen-by-specimen basis, further increasing the leverage of Medicare program reimbursement decisions.

Medicare's payment method for ambulatory laboratory tests depends both on the setting in which a test is ordered (i.e., whether hospital outpatient department or physician's office) and the setting in which it is performed (hospital, physician's office, or independent laboratory).

Before July 1984, Medicare payments for tests ordered during physician office visits were made on a reasonable-charge basis under Part B, the Supplementary Medical Insurance program. Payment for these services was 80 percent of the reasonable charge, after the beneficiary had met an annual deductible payment (currently $75). The reasonable charge for a laboratory test was determined by a CPR method of screening claims similar to that applied to physicians' fees. The reasonable charge for a laboratory test, regardless of where it is performed, is the lowest of the five following separate limitations:

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[12] The material presented in this section is based on a background paper prepared for OTA by Foster (120).

- the *actual charge* billed for the service by the physician or laboratory;
- the *customary charge* of the laboratory or physician for the test, calculated as the provider's median charge in the previous year;
- the *prevailing charge* in the locality, computed as the 75th percentile of all customary charges for all participating laboratories or physicians;
- the *lowest charge* at which the test is widely and consistently available (currently established for 12 common laboratory tests; or
- the *comparable charge* paid by the private insurers that serve as the Medicare carrier.

The customary charges of hospitals, physicians' offices, and independent laboratories, regardless of whether they use automated equipment, were commingled to calculate the prevailing charge in the locality, and all kinds of providers of such services were subject to the same prevailing charge or lowest charge limitation. Note also that this procedure generally resulted in Medicare's paying laboratories at a low rate relative to private insurers.

Medicare can pay one of three different entities for ambulatory tests: the beneficiary, the test-ordering physician who has accepted assignment, or the testing laboratory that has accepted assignment (42 CFR, sec. 405.251(b)). Until a recent change in the law, if the beneficiary sought reimbursement, he or she would receive from Medicare 80 percent of the laboratory's reasonable charge, less any deductible. The party billing the beneficiary (whether it be a physician's office, hospital, or independent laboratory) was subject to no limitation on the amount that could be charged the beneficiary, who had to make up the difference.

Under this method of payment, the physician was in a unique position of having the power not only to choose whether or not to accept assignment and bill Medicare directly, but also whether to perform a test in the office or send the specimen to an independent or hospital laboratory. If the physician accepted assignment, the amount Medicare would pay depended on the information supplied on the physician's claim for reimbursement. If the claim indicated that the test was performed in the office, Medicare would pay the physician 80 percent of the reasonable charge as described above. If the claim indicated that the test was performed by an outside laboratory, Medicare would pay the physician only the laboratory's reasonable charge plus a $3 handling fee.

Before July 1984, Medicare reimbursement for tests ordered during hospital outpatient visits was based on 80 percent of the cost of the service to the hospital and 80 percent of the reasonable charge for any physician service provided in connection with the test. (The patient was responsible for paying the remaining 20 percent.) Since October 1983, HCFA treated most clinical laboratory tests performed in hospital laboratories not as physicians' services but as hospital outpatient services. Consequently, the price was typically based on the cost, not the charge, method.

In July 1984, Public Law 98-369 established a new method for setting ambulatory laboratory fees that represents a significant departure from the traditional method described above. For a 3-year period beginning in 1984, Medicare payment for laboratory services will be established at a fixed percent of the prevailing fee level (60 percent for physicians' offices and independent laboratories, 62 percent for services to hospital outpatients). After 3 years, a national fee schedule, presumably departing from the prevailing charge, will be developed.

The new law expressly forbids physicians from billing for laboratory services unless they are actually performed in the physician's office. Physicians who conduct their own tests can still choose whether to accept assignment, but the law contains a provision to encourage assignment. When a physician accepts assignment, Medicare reimbursement will be at 100 percent of the fee schedule amount (rather than 80 percent) and the coinsurance and deductible will be waived.

Independent laboratories must accept assignment, but Medicare will pay 100 percent of the fee schedule and will waive coinsurance and deductible requirements. The handling fee (currently $3) will be available to the physician or laboratory that collects the specimen.

Overall, Medicare's payment method for laboratory tests encourages physicians to perform tests in their own offices, especially when the expected per-test profit exceeds the $3 handling fee (i.e., when the Medicare payment level plus additional payment by the patient exceeds per-test costs in physicians' offices by at least $3). Whether this condition is met depends on the technical costs of performing specific tests and the strength of economies of scale in their production.

Tests requiring a heavy fixed investment in capital equipment may be economical only for the highest volume group practices. But performing tests in physicians' offices eliminates transportation costs required of outside laboratories and the extra costs associated with laboratory licensure standards, to which physicians are not obligated in most States. The recent emergence of simple, inexpensive laboratory equipment and test kits that can be operated at a profit at low volumes has opened up a wide new physicians' office market that clinical laboratory equipment manufacturers are seeking to fill (35).

The encouragement of testing in physicians' offices, although an important new market for manufacturers, may not be the most rational use of health care resources for two reasons. First, there are situations in which the physician has a financial incentive to select the more costly setting. For example, suppose the fee schedule rate for a test is $9 and the cost of the test performed in an independent laboratory is $4.50 (including transportation), while a physician can produce the same test at a cost of $5. Under both the old and new reimbursement methods, the physician has an incentive to produce the test in-house, regardless of the higher cost. When it is recognized that the physician can refuse assignment on a claim-by-claim basis and charge the patient more than $9, the financial incentive to perform the test in the office appears even stronger. Also, by expressly forbidding physicians from billing for services provided by independent laboratories, the new law will further strengthen the incentive for testing in physicians' offices.

Second, there is suggestive evidence that tests performed in physicians' offices may be of lower quality than are tests performed by independent laboratories (132a,183,212). Data from a national proficiency testing program conducted by the American Association of Bioanalysts revealed that physicians' office laboratories in the program produced substantially less precise and accurate test results than did independent laboratories (132a, 183). However, the introduction of automated laboratory technology may improve physician laboratory performance in the future.

Medicare's payment system also encourages hospitals to expand their laboratory services to outpatients and nonhospital patients. The new prospective hospital payment system, which pertains only to inpatients, creates strong pressures for hospitals to maximize the proportion of their laboratory tests conducted on outpatients in order to allocate as many costs as possible to (and reap as high revenues from) this less restricted payment area. And to the extent that hospitals can compete for business with independent laboratories, this additional source of revenue will further help offset the laboratory-associated costs.

However, Medicare's new laboratory payment system may encourage some hospitals to refer the bulk of their inpatient testing to highly automated independent laboratories with competitive prices in order to reduce inpatient costs. Thus, the role of the hospital laboratory in the ambulatory laboratory testing market appears to be undergoing fundamental changes—with the precise outcome unknown at this time.

Payment for Medical Devices Used in the Home

Medical devices used in the home include a wide range of products—from disposable supplies such as bandaids, incontinence aids, and pregnancy tests, to long-lasting equipment such as wheelchairs and hospital beds. Third-party coverage of a device used in the home depends on specific characteristics of the device and the patient. From the standpoint of payment, four different kinds of medical devices are:

- *Self-administered medical devices*—devices such as bandages, incontinence aids, thermometers, blood pressure monitors, or over-the-counter tests. These products are chosen by consumers, not physicians, and most third-party payers do not cover them. There are some exceptions if the devices are prescribed by a physician.
- *Durable medical equipment (DME)*—equipment that can stand repeated use; is generally not useful in the absence of illness; and is appropriate for use in the home. These devices are generally covered, provided they are prescribed by a physician.
- *Home health care devices*—devices used in conjunction with health care services rendered in the home by health care professionals. Medicare and Medicaid cover these devices, but their coverage by private insurers varies.
- *Home renal dialysis devices*—equipment and supplies used to provide home renal dialysis to patients with end-stage renal disease. These devices are covered by Medicare, with supplementary coverage provided by some private insurers.

Self-administered medical devices, if ordered without a prescription, are rarely covered by third-party payers; consequently, they can be considered traditional consumer goods and will not be discussed in detail except to note that the lack of insurance coverage for such devices puts them at a disadvantage relative to devices provided by physicians or other professionals. If these devices are ordered by prescription, they are sometimes covered under insurance policies, usually to the same degree that devices provided in a physician's office would be covered. Self-administered devices will be demanded if their purchase price and the convenience they represent is competitive with the out-of-pocket costs and convenience of using alternative devices that are covered by third-party payers.

Renal dialysis devices used in the home are unique in that they are covered by a uniform Medicare payment system: Medicare's End Stage Renal Disease (ESRD) program. Since 1972, Medicare benefits have been available to all patients regardless of age. The effect of the payment system on the kinds and prices of available dialysis equipment and supplies, as well as on the settings in which they are used, has been profound. A separate case study prepared for this report examines hemodialysis devices in detail (see box E) (260).

The two other kinds of devices—durable medical equipment and devices provided as part of home health care services—raise some interesting issues for Federal payment policy and are discussed in detail below.

Payment for Durable Medical Equipment

Hospital beds, wheelchairs, oxygen and its related equipment, canes, and crutches are examples of DME. The Inspector General of DHHS has projected total national (public and private) expenditures for DME to reach $1.26 billion to $1.58 billion in fiscal year 1985 (160). In 1982, Medicare outlays for DME were about $310 million (158), up almost 150 percent from $125 million in 1979 (333).

These estimates do not include durable equipment provided to Medicare patients as part of home health services, estimated at about $19 million in 1982 (158). Table 20 shows the distribution of spending for various types of DME by a sample of Medicare beneficiaries in 1977. Interestingly, oxygen and oxygen equipment alone accounted for 46 percent of total expenditures for rental and purchase of DME. Medicare expenditures for DME may increase even more with the advent of DRG payment for hospitals. The incentive for hospitals to discharge patients early to the home may lead to greater use of DME in the recovery period.

DME is a distinct benefit category under Medicare's Supplementary Medical Insurance program (Part B of Medicare). Medicare generally covers 80 percent of the "reasonable" charge or cost of

Box E.—Medicare Payment for Renal Dialysis: Effect on Medical Devices[1]

End-stage renal disease (ESRD) afflicts about 83,000 people in the United States (98). In the course of treatment for this disease, most patients and their providers use an array of products produced by the hemodialysis equipment and supplies industry. This industry is relatively new. Its whole existence is a consequence of modern medical advances that have made hemodialysis a viable treatment for ESRD.

For patients with ESRD, the major alternative to kidney transplantation is dialysis, which offers an artificial mechanism for performing kidney functions. In *hemodialysis*, blood is pumped from the patient's body, subjected to a process of dialysis, and then returned to the body in a continuous extracorporeal blood loop. Patients on hemodialysis are typically dialyzed three times per week, for sessions ranging from about 3½ to 5 hours each. These patients can be dialyzed at home or in hospital-based or freestanding dialysis facilities or centers. Hemodialysis was the treatment for about 89 percent of the patients with ESRD in 1982 (98).

Another form of dialysis, *peritoneal dialysis*, has been increasing in popularity in recent years. In peritoneal dialysis, the process of dialysis occurs within the patient's body rather than via an extracorporeal blood loop. Continuous ambulatory peritoneal dialysis (CAPD) involves a continuous dialysis process and frees the patient from dependency on a machine. Used by about 10 percent of the ESRD population in 1982, CAPD is the most popular form of peritoneal dialysis (98).

Since July 1973, the Medicare program has covered about 93 percent of the ESRD patient population (78). ESRD patients are enrolled under Parts A and B of the Medicare program. Part A (Hospital Insurance) covers the reasonable and necessary services received in a participating facility, including inpatient dialysis. ESRD patients generally receive dialysis on an outpatient basis, covered by Part B (Supplementary Medical Insurance). Under Part B, ESRD beneficiaries pay a monthly premium and are entitled to payment of 80 percent of reasonable charges or costs above a deductible. Patients are responsible for the remaining 20 percent of charges.

Home dialysis has been covered under this same basic arrangement. Medicare pays 80 percent of allowed costs for supplies and equipment and physicians' services above the deductible. Since 1978, if the patient obtained home dialysis and equipment from an approved facility that reserved the equipment for the exclusive use of patients on home dialysis, the 20-percent coinsurance requirement has been waived.

In establishing the actual levels of payment for dialysis, the Medicare program had few precedents. The early decision was to pay 80 percent of the average cost to a hospital-based dialysis facility, and 80 percent of the reasonable charges for a freestanding dialysis facility up to a screen (or limit) of $133 per treatment. If routine laboratory services were included, the screen was raised by an additional $5; if the supervisory services of a physician were included in the facility's costs, the screen was increased by $12, to $150. These rates were in effect from 1974 until August 1983, when they were supplanted by a new reimbursement method.

In 1982, prior to the new rules, nearly all freestanding facilities were being paid at the rate of $138 per treatment (78). Most hospital-based facilities requested and were granted exceptions to the screen, on the grounds that their costs were higher; the average hospital-based payment in 1982 had risen to approximately $170 per treatment (78,356).

Under the old system, physicians could choose from one of two systems of payment: the initial method and the alternative reimbursement method. Under the initial method, reimbursement for supervisory care was paid to a facility as part of its reimbursement rate. Other nonsupervisory services were paid on a fee-for-service basis. Under the alternative method, physicians were paid a comprehensive monthly fee per patient. For patients dialyzed in facilities, this fee was based on a calculation of the customary or prevailing charges for a followup visit, multiplied by 20. For supervision of home patients, the weighting factor was set at 14 rather than 20, to reflect the presumed lower requirements of home patients for physician supervision.

Section 1881 of the End Stage Renal Disease Amendment of 1978 (Public Law 95-92) established a new prospective reimbursement method for dialysis facilities. The final rules under this system, which became effective August 1, 1983, established average payment rates of $131 for hospitals and $127 for freestanding facilities regardless of whether dialysis occurs in the center or at home (316). (Adjustments were made for geographical wage differentials.)

Fixed rates such as these are designed to encourage facilities to control costs. Any excess of the rates over incurred costs can be kept by the facility; any deficit in costs must be absorbed. In addition, the composite nature of the rates is intended to create an incentive for movement toward increased home dialysis. One way for a facility to reduce costs is to lower the cost of materials and equipment used in the dialysis process. This can be accomplished by pressuring manufacturers to lower the prices they charge. In general, there has been little upward movement in prices in this market, and prices for at least one key product, dialyzers, have actually fallen (260). However, variation remains in prices paid by users. More concerted efforts by buyers are likely, through more strenuous bargaining, forming cooperative buying ventures, or other means.

Materials costs can also be reduced by increased use of dialyzers. The practice of reusing dialyzers has grown rapidly in recent years. About 25 percent of the freestanding facilities reuse dialyzers, compared with only 1 percent of the hospital-based facilities (78). Although manufacturers state that today's dialyzers were designed for single use only (457), reuse is a fact. Cost pressures may stimulate design changes that enhance the efficiency or reduce the costs of reprocessing. Also, because reuse raises a facility's labor costs by requiring extra handling of dialyzers, manufacturers may be stimulated to develop automated dialyzer reprocessing equipment.

The incentive for home dialysis under the new rules should create some movement toward increased home dialysis. What effects would this have on the industry? If the movement was simply from in-center hemodialysis to home hemodialysis, the effects would probably increase sales. Equipment and disposables requirements would be technically similar. However, patients at home would not be able to share machines as they would in facilities. Without this opportunity to economize on machines, more machines would be demanded for any given patient population.

However, most new home patients are choosing CAPD (40), although not all ESRD patients can use this modality. Firms that have a firm foothold in the market may gain at the expense of others that do not. At the same time, many firms focusing on hemodialysis will be encouraged to diversify into CAPD products (186,271).

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[1] The material presented is based on a case study of the hemodialysis equipment and supplies industry prepared for OTA by Romeo (260).

this equipment, subject to the annual deductible amount. In practice, the reasonable charge is determined by the CPR method described in sections above. The allowed rate of payment for a particular item of DME is the minimum of the DME supplier's actual charge, the supplier's customary charge (the median of supplier's own past charges) or the prevailing charge, defined as the 75th percentile of all purchase or rental charges for the particular device in the locality during the preceding year.[13]

If the supplier agrees to accept the Medicare reasonable charge as payment in full (i.e., accepts assignment), then the Medicare enrollee is liable only for his or her 20-percent coinsurance plus any deductible owed. But if the supplier does not accept this payment, the beneficiary must pay the difference between the reasonable charge and the

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[13] The DME reimbursement system is currently under scrutiny by HCFA and the General Accounting Office for its effects on users' decisions whether to purchase or rent equipment (92,156,157,237, 333). Uncertainty about the duration of use of DME is inherent in the nature of the service, but Medicare's current system of payment provides inadequate incentives for users to purchase equipment, even when it is fairly clear that such a decision would cost Medicare less than rental. Although the issue has important implications for Medicare expenditures, it does not influence choices among devices or the overall rate of use of devices in any fundamental way and is not discussed in this report.

Table 20.—Durable Medical Equipment (DME) Rental and Purchase Reimbursement Expenditures, by Major Category, All Participating Carriers, 1976 and 1977[a]

	1976				1977			
	Rental		Purchase		Rental		Purchase	
Category description	Dollars	Percent	Dollars	Percent	Dollars	Percent	Dollars	Percent
Hospital beds and accessories	$1,591,925	26.53%	$ 520,023	9.85%	$ 798,338	19.43%	$ 867,895	13.81%
Commode chairs, bedpans, urinals, and toilet accessories	232,862	3.88	158,948	3.01	148,765	3.62	218,369	3.47
Canes, crutches, and accessories	31,149	0.52	31,656	0.60	33,919	0.83	24,887	0.40
Traction equipment and accessories	175,114	2.92	77,044	1.46	75,780	1.84	108,429	1.73
Walkers and walking aids	202,821	3.38	170,110	3.22	151,566	3.69	172,573	2.75
Wheelchairs and accessories	1,091,624	18.19	536,966	10.17	736,903	17.93	644,866	10.26
Oxygen	—	0.00	2,598,333	49.21	—	0.00	2,323,585	36.98
Pads and cushions	147,831	2.46	25,911	0.49	45,628	1.11	91,427	1.45
Miscellaneous DME	16,570	0.28	18,077	0.34	188,614	4.59	19,450	0.31
Oxygen therapy equipment	1,963,170	32.72	816,872	15.47	1,183,791	28.81	1,349,534	21.48
Repair/maintenance	347,758	5.80	40,611	0.77	344,094	8.38	36,201	0.58
Unspecified DME	199,920	3.33	285,558	5.41	401,552	9.77	426,464	6.79
Total	$6,000,744	100.01%	$5,280,109	100.00%	$4,108,950	100.00%	$6,283,680	100.01%

[a] Data not included from Equitable Tennessee for 1977 or from Washington Physicians Service from Nov. 1 through Dec. 31, 1977.

SOURCE: T. J. Janssen and G. T. Saffran, "Reimbursement for Durable Medical Equipment," *Health Care Finan. Rev.* 2(3):94, winter 1981.

actual price of the equipment. The decision whether to accept assignment rests with the supplier on a case-by-case basis.

In addition to being generally inflationary, Medicare's CPR pricing system creates particular problems in localities with only one or a few suppliers of DME. A high-priced supplier with at least 25 percent of the locality's market for a particular kind of DME can unilaterally determine the prevailing charge and thus manipulate its payment rate (237). The only deterrent to such behavior is the 20-percent coinsurance rate, which may make some consumers sensitive to the price charged. But in localities with just one or two suppliers, this price sensitivity is bound to be low.

Some observers have noted the potential impact of Medicare's hospital DRG payment system on the suppliers of DME (154). Under DRG payment, hospitals have an incentive to become suppliers of services and products that are subject to less restrictive payment. One potential is for these institutions to become DME suppliers. Having a built-in referral base of patients would facilitate this kind of service integration.

The net effect of competition from hospitals on DME prices is unknown, but it could conceivably cause price cutting by freestanding suppliers in an attempt to maintain their market share. However, the sensitivity of patients to changes in DME prices may be low because the effective coinsurance rate for DME in 1977 was estimated at 26 percent (237). Independent suppliers appear to be concerned about the possible effects of competition from hospitals with a "captive" market (161) and have suggested that Medicare require hospitals to provide patients with information on independent suppliers.

Payment for Home Health Care Services

Home health care services are defined as services that require professionally trained personnel (e.g., nursing, physical therapy) and are delivered to patients in the home. To some extent, home health care substitutes for institutional care provided in hospitals and nursing homes, but in part it is also a service that substitutes for care that would otherwise be provided by family, friends, or patients themselves. Since medical devices are commonly used in the delivery of these services the recent rapid growth in the use of home health care services will affect the kinds of devices that will be demanded.

Although there are no precise data on historical trends in the total use of home health care services throughout the country, data are available for use by Medicare and Medicaid beneficiaries. From 1974 to 1982, the number of home health visits to Medicare beneficiaries increased by 247 percent, from 8.1 million visits in 1974 to 28.1 million visits in 1982 (159). In the same period, Medicare reimbursements to home health agencies—organizations that provide home health care services—grew from 1.2 to 2.5 percent of total Medicare reimbursements, or $1.2 billion in 1982. Approximately 4 percent of those reimbursements were for equipment, appliances, and nonroutine supplies offered as part of home health care visits (136), and 28 percent can be attributed to nonlabor costs (310). Medicaid expenditures for home health services were almost $500 million in 1982 (399).

Table 21 estimates national home health care expenditures by source in 1981. Since the data underlying these estimates are imprecise, the table should be considered only as a general description of the relative importance of various funding sources. Almost 60 percent of home health care expenditures are paid for directly by patients. Medicare and Medicaid account for another 19 percent of such expenditures, and private insur-

Table 21.—Estimated Home Health Care Expenditures[b] and Percent Distribution by Source, 1981

	Dollar amount (billions)	Percent of total
Patient direct payments	$3.8	58.5%
Medicare	0.9[a]	13.9
(Federal)	0.3	4.6
(State)	(0.2)	(3.1)
Other government	0.3	4.6
Private health insurance	1.1[b]	16.9[b]
Philanthropy	0.1	1.5
Total	$6.5	100.0%

[a] This is an understatement because it includes approximately one-tenth of expenditures provided through hospital-based home health care services.

[b] A proxy was used for expenditures for "home health care." The proxy used, reimbursement for "other payment services," generally reflects government and patient direct payments for home health care, but may not accurately reflect private health insurance coverage, which is probably much lower than the 16.9 percent indicated in the table.

SOURCE: R. M. Gibson and D. R. Waldo, "National Health Expenditures, 1981," *Health Care Finan. Rev.* 4(1):1-35, September 1982.

ance for less than 17 percent. These data are for 1981, before expanded Medicare home health benefits as mandated by the Omnibus Budget Reconciliation Act of 1980 (Public Law 96-499) were implemented. Medicare's share of home health care expenditures may have increased since then.

The number of home health agencies has grown dramatically in the past 3 years alone. Table 22 shows the number of Medicare-certified home health agencies by type in 1979, 1981, and 1982. Substantial growth occurred in the number of proprietary agencies serving Medicare patients. Part of the reported growth between 1981 and 1982 does not represent development of new agencies but is an artifact of the liberalization of Medicare's policy regarding certification of proprietary agencies that went into effect in October 1981 pursuant to the Omnibus Budget Reconciliation Act of 1980. But even between 1979 and 1981, when proprietaries were unable to participate in Medicare in certain States, the number of these agencies serving Medicare patients grew by almost 75 percent.

Medicare will pay for home health services to patients who are homebound, under the care of a physician, and requiring part-time or intermittent skilled nursing care or physical or speech therapy. There are no deductibles or coinsurance required of the beneficiary, and since 1980, there are no limits on the number of visits the beneficiary can receive during any year. Medicare reimburses home health agencies on a reasonable cost basis, much the same as the Medicare inpatient hospital reimbursement method prior to the introduction of DRG payment. In the recent past, attempts to control Medicare outlays for home health services have centered on two strategies: 1) tight control over eligibility for home health care services, and 2) imposition of per-visit limits on rates of reimbursement to home health agencies.

To be eligible for home health care benefits, the patient must require "intermittent" skilled nursing care. The definition of skilled nursing care depends on the licensing requirements of the individual States; usually it means a person with a Registered Nurse or Licensed Visiting Nurse or equivalent degree. The definition of "intermittent" has been the major avenue for control. HCFA has recently interpreted it to mean a requirement for up to two or three visits per week and less than 8 hours in any one visit. Daily visits by a skilled nurse are reimbursed only if a physician affirms that such frequent visits will not be necessary for more than 2 or 3 weeks (74). The idea is that if a patient needs daily care, he or she should be in a skilled nursing home, even if the person would prefer to stay at home, because it is less expensive (162).

Medicare does not provide home health care benefits to patients who receive total parenteral or enteral nutrition therapy at home. But, since 1977, Medicare has covered these services under its prosthetic device benefit (Part B), which covers all nutrients, equipment, and supplies. HCFA has interpreted the prosthetic device benefit as requiring the patient to have severe and permanent impairment and as not covering the nursing serv-

Table 22.—Medicare-Certified Home Health Agencies by Type of Agency

Type of agency	December 1979	September 1981	December 1982
Visiting nurses association	511	513	517
Combination (government/voluntary)	50	55	59
Government	1,274	1,234	1,211
Rehabilitation center based	NA[a]	11	16
Hospital based	349	432	507
Skilled nursing home based	NA[a]	10	32
Proprietary	165	287	628
Private nonprofit	443	547	632
Other	66	38	37

[a] NA indicates information not available; home agencies in these categories were classified as "other" in 1979.

SOURCES: **1979 data:** U.S. Department of Health and Human Services, Health Care Financing Administration, Office of Research and Demonstration, *Medicare: Use of Home Health Services, 1980*, prepared by Kathryn D. Barrett, July 1983 draft; **1981, 1982 data:** *Home Health Line*, "Changing Face of Medicare Home Health" (table), vol. VIII, p. 28, Feb. 4, 1983.

Photo credit: American Society for Parenteral and Enternal Nutrition, Inc.

This portable parenteral nutrition system, which pumps nutrients directly into the bloodstream, is being used by a woman in her home. Medicare pays for parenteral nutrition therapy provided in the home only for people with permanent impairment.

ices, delivery charges, or refrigerator for nutrient storage. Some home health agencies have complained that these restrictions shift potential nutrition services away from them to suppliers of Part B services, such as retailers of such medical equipment and supplies, and also discriminate against patients requiring home health care as well as nutrition services (153). (See box F for a description of the parenteral and enteral nutrition market.)

Control over rates of reimbursement to home health agencies was initiated in 1981 (310) and tightened again in 1981 and 1982. The control was in the form of limits on per-visit routine costs of home health agencies. At present, all home health agencies are subject to a per-visit limit set at the 75th percentile of costs of freestanding agencies, weighted by the mix of visits made (skilled nursing, physical therapy, home health aids) and the urban or rural location of the agency. The cost of medical equipment, appliances, and supplies that are not routinely furnished in conjunction with patient care visits are not subjected to the limits.[14]

The reimbursement limits have several inherent incentives. The most obvious is for the home health agency to "unbundle" its supplies from routine categories to nonroutine categories, which are not subject to payment limits. The second is to substitute nonroutine equipment, appliances or supplies for routine nursing or other services whenever possible. Third, the agency has no incentive to consider price in decisions to purchase nonroutine items. The ultimate effect of these limits is probably to increase the use and cost of medical devices in home health care.

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[14] Medical supplies that are not routinely furnished in conjunction with patient care visits and are directly identifiable services to an individual patient must meet the following criteria: 1) the common and established practice of home health agencies in the area is to charge separately for the item; 2) the agency follows a consistent charging practice for both Medicare and non-Medicare patients receiving the item; 3) generally, the item is not frequently furnished to the patient; 4) the costs can be identified and accumulated in a separate cost center; and 5) the item is furnished at the direction of the patient's physician and is specifically identified in the plan of treatment (310).

Box F.—Parenteral and Enteral Nutrition Therapy

Parenteral and enteral nutrition are relatively recently developed medical technologies that depend on medical devices for their use. Parenteral nutrition refers to the intake of nutrients directly into the bloodstream, circumventing the digestive tract. Enteral nutrition refers to the intake of nutrients into the stomach or small intestine via a catheter or nasal tube (10). Enteral nutrition is the preferred approach for persons who retain the use of their lower alimentary tract because it is both safer and cheaper than parenteral nutrition (59). Sometimes referred to as hyperalimentation, these technologies have as their primary goal the elimination of malnutrition in those patients who cannot adequately digest food or whose nutritional needs are elevated due to injury or disease.

For parenteral nutrition, the infusion setup consists of the nutrient solution; nondisposable equipment, such as the intravenous (IV) pole and infusion pump; and disposable supplies, such as the IV administration set and infusion cassettes. Prior to the late 1960s, prolonged maintenance of patients who could not adequately digest food was not possible. The development of hyperalimentation came about through advances in four areas: greater knowledge of human nutritional needs, improved surgical procedures for insertion of catheters, improved catheter composition and design, and improved infusion control devices.

Parenteral and enteral nutrition can be delivered either in the hospital or, when the conditions are right, in the home. In either setting, they represent expensive therapies, especially in the long term. Rough estimates of 1982 per-patient charges for these therapies are as follows (10):[1]

	Parenteral		*Enteral*	
	Home	*Hospital*	*Home*	*Hospital*
Charges per day	$125-$250	$300-$600	$30-$60	$150-$300

The most important factor in cost appears to be the quantity of disposable supplies, including nutritional solutions which account for almost 90 percent of the total cost. Other studies have estimated costs of a typical parenteral patient at home to be about $40,000 to $50,000 per year (147,189,283). A recent study of Medicare reimbursements for home hyperalimentation revealed substantial variation among sampled patients in the amounts billed by suppliers and paid by Medicare. For parenteral nutrition, the amounts billed by suppliers ranged from $3,046 to $4,122 per month, and enteral nutrition billings ranged from $346 to $1,130 per month (162).

Estimates of the number of patients receiving hyperalimentation nationally are imprecise but have been approximated for 1982 as follows (10):

	Parenteral		*Enteral*	
	Home	*Hospital*	*Home*	*Hospital*
Number of patients	2,000-5,000	200,000	5,000	2,000,000

Major issues involving payment policy are currently outstanding and have an important impact on the amount and location of hyperalimentation services. Payment for these technologies in the hospital is straightforward. Most third-party payers, including Medicare and Medicaid, pay for hyperalimentation as they do for any service delivered to inpatients. In 1977, Medicare began to cover home hyperalimentation on the advice of the Public Health Service. Because IV nutrients are classified as drugs and are therefore not individually reimbursable under Medicare's Part B (Supplementary Medical Insurance) benefit, the Medicare program declared all of home hyperalimentation a prosthetic device and therefore subject to Part B coverage. However, the prosthetic device benefit is generally reserved for those with permanent impairment and therefore does not cover those with temporary need for this technology. The Health Care Financing Administration is currently considering liberalizing the definition of permanent impairment to include long-term disabilities, but proponents of home hyperalimentation claim that this will still deny home coverage to those with short-term problems.

For example, patients requiring surgery who have lost more than 20 percent of their body weight generally represent higher surgical risks and may benefit from a short course of hyperalimentation prior to the operation (290). These patients would not be covered for hyperalimentation in the home and would most likely receive such services in the hospital prior to surgery. However, since hyperalimentation is an expensive therapy, its use in the hospital may also be discouraged by Medicare's new per-case payment method based on diagnosis related groups (DRGs).

The use of hyperalimentation as an adjunct to cancer therapy illustrates the difficulties facing those who make payment policy. Under what conditions and for what kinds of patients is hyperalimentation effective and safe and therefore worthy of payment? At present there is a great deal of controversy over the effectiveness of nutrition support in cancer patients except to assist in the recovery from side effects of anticancer therapies (such as radiation enteritis) (44). Under DRG payment, hospitals can be expected to become more conservative in the application of the technology, given its high daily cost. Lacking home coverage, patients (or their physician advocates) would also be conservative about its use in marginal situations. However, if Medicare covered short-term nutrition support, the procedure might be used more frequently for indications for which definitive medical benefit has not been established.

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[1] These are rough estimates only; they are not based on primary data collection.

THE FINANCIAL RELATIONSHIP BETWEEN THE THIRD-PARTY PAYER AND PROVIDERS

The vast majority of health care services in the United States are delivered by private providers—hospitals, physicians, and other professionals and institutions—who are organizationally and financially independent of the third-party payer. As discussed above, these providers bill either the patient, the third-party payer, or both and are paid some proportion of their costs or charges, depending on the payment methods and policies of the third-party payer. This fee-for-service system pays providers more when more services are delivered. Except for those services whose level of payment is below their cost,[15] the provider is financially rewarded by providing more services. Although the third-party payer can attempt to control the use of services through regulatory means, such as utilization review, the provider has a general incentive to deliver more individually billable services.

There are two exceptions to this fiscal independence of payer from provider. First, for health services that are provided directly by the government in publicly owned and operated facilities, the payer and provider are integrated in the same entity. The VA's system of hospitals, nursing homes, and outpatient clinics is an example of an integrated health care system that is relatively closed and publicly funded and operated. Second, a small but growing proportion of the population is enrolled in per capita insurance plans.

Public Systems

Whether the patterns of use of health care services and, hence, of the devices on which many of them depend are substantially different in publicly operated and budgeted facilities is a matter for empirical investigation. There is some circumstantial evidence suggesting that the rate of adoption of certain new medical devices has been slower in VA hospitals than in the civilian health care sector, but differences between public and private administration confound the comparison. VA hospitals adopted CT scanners much more slowly than other hospitals of comparable size. In 1980, almost 85 percent of all community hospitals of 500 beds or more had at least one CT scanner, whereas only 25 percent of VA hospitals of comparable size had adopted CT scanning (349).[16] In the remaining hospitals, the VA contracted with civilian hospitals for provision of CT procedures.

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[15] There are several reasons why the level of payment might be below the cost of providing a service to a given patient. First, the cost of providing the service might vary randomly around some mean level, thus leading to losses on some patients, which are made up for by profits on others. Second, the service might be a "loss-leader," deliberately priced low to encourage utilization of other, more profitable services. Third, the provider may be required to offer some services below cost as a condition for providing others to a third-party payer's beneficiaries.

The rate of use of therapeutic apheresis also appears to be substantially lower in VA hospitals than in the civilian sector, although no comparisons by type of patients treated are available to pursue the reasons for the difference (350). A study conducted in the early 1970s of hospitals' adoption of respiratory therapy techniques and electronic data processing found that Federal hospitals adopted these technologies more widely than non-Federal hospitals, but the study did not control for hospital size, the population served, and other important differences between Federal and non-Federal hospitals (187). (Federal hospitals on average are much larger than non-Federal hospitals.)

Per Capita Payment Systems

The second exception to the fiscal independence of payer and provider covers a small but growing proportion of the population (5.8 percent in January 1984 (170)) enrolled in health maintenance organizations (HMOs). For a fixed per capita payment, HMOs provide comprehensive but specified covered medical services through a defined set of physicians and hospitals (346). An HMO may either employ or contract with physicians to provide the covered services. If the relationship is contractual, it may be on a basis other than simple fee-for-service. Although an HMO may own its hospital, almost all contract with selected hospitals and other facilities to provide services to their enrolled members. Since the HMO must compete with other insurers, it has an incentive to keep premiums competitive with them. HMOs are also organizationally well suited to limiting costs by controlling the use of covered services.

There is strong evidence that enrollees of prepaid group practices, a type of HMO organized around a medical group practice, have lower rates of hospitalization than other plans. In a review of HMO experience, Luft concluded that enrollees in prepaid groups had about 30 percent fewer hospital days, mainly because of lower admission rates rather than shorter lengths of stay (198). But studies of HMOs organized around contracts with independent physicians, frequently referred to as individual practice associations (IPAs), do not support the contention that these have lower hospitalization rates when differences among patient characteristics are considered (346). In general, IPAs and other HMOs appear to have lower rates of surgery than fee-for-service plans (346).

The lower rates of hospitalization in prepaid groups would, of course, lower the use of medical supplies and equipment in the hospital. Surgical supplies and equipment, in particular, would need to be bought less frequently under an HMO payment system. Of course, to some extent reductions in the use of hospital devices may be accompanied by more intensive use of device-embodied procedures during ambulatory care visits.

The net effect of these shifts has not been studied, but it is likely that the direct impact of HMOs to date on the medical devices industry or any of its segments is probably small.[17] Although the competitive effect of HMOs on the behavior of other private insurers could reduce the rate of use of health services more generally in the community, particularly in those metropolitan areas where HMOs have a significant share of the insurance market, there is no convincing evidence that such an effect has occurred (198). This result is not surprising considering that HMOs, as well as other plans, have been operating in an environment where the buyers of health insurance and medical care are insulated from market pressures to be efficient.

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[16] Most VA medical centers, for example, include chronic care beds, whereas most community hospitals do not.

[17] As of January 1984, 5.8 percent of the civilian population was enrolled in HMOs, and in 1981, about 84 percent of HMO enrollees were in prepaid group practices (170). If prepaid group practices account for a 30-percent reduction in days of stay per capita, the existence of prepaid group practices is responsible for at most a reduction of 1.5 percent in total patient days.

The appeal of HMOs and other prepaid plans is that they hold promise for more careful assessment of all inputs into the production of health care services, including devices. HMOs have incentives to provide care in the most efficient and cost-effective manner, using the best mix of resources to accomplish that purpose. But there are also pitfalls. HMOs have an incentive to enroll healthy members of the population whose medical care is less costly to provide. Such practices also have a financial incentive to provide as few services as possible to their enrollees. As long as HMOs exist in an environment in which they must compete for members, however, the tendency toward underprovision of services may be limited.

DISCUSSION AND POLICY OPTIONS

This chapter has examined the relationship of third-party payment, particularly Medicare, to the overall size of the medical devices market and the kinds of medical devices that are likely to be bought and used. In the traditional fee-for-service sector of U.S. health care, the decision to cover a particular device and the methods used to determine the amount of payment appear to influence the demand for devices.

The methods used to determine levels of payment for devices or device-embodied medical services have influenced their adoption and use in ways that will increase society's cost without adequate concern for benefits. In particular, the reasonable charge approach used by Medicare for all Part B services creates problems in several areas. With physicians' services it tends to favor new device-embodied procedures over traditional technologies and office visits, with inadequate regard for their relative cost effectiveness. For laboratory testing, the CPR mechanism tends to encourage laboratory testing in physicians' offices. And for durable medical equipment, suppliers with a high share of the market may be able to manipulate payment rates.

Although cost-based reimbursement of hospitals is being largely discarded by Medicare, and may soon disappear for other payers as well, the continuation of cost-based reimbursement of hospital capital tends to favor medical equipment over other kinds of resources used in the delivery of hospital services. In addition, the cost-based system continues to apply to Medicare home health services, creating incentives to use medical devices (as well as other inputs to home health services) that may be socially inefficient. Although Medicare has instituted limits on per-visit costs, they do not include nonroutine supplies, equipment, and appliances provided as part of a physician's plan for home health services. Thus, there are additional incentives for home health care to become too device-intensive over time.

It appears that the manufacturers of medical devices may be responsive to changes in third-party payment policy, particularly Federal payment policy, in the kinds of devices that are made and the prices at which they are sold. Even in concentrated markets, such as that for hemodialyzers, manufacturers appear to have been responsive to market pressures by reducing prices or improving products to enhance their productivity (260). The recent introduction of Medicare's DRG payment system may lead to substantial changes in the kinds of devices that are marketed to hospitals. The ultimate impact of these changes on the total market for medical devices is, of course, unknown—as are their ultimate effects on the quality and costs of medical care.

The problems discussed above can be addressed on a piecemeal basis by altering details of third-party payment methods, or they can be addressed by broader reforms of the payment system. The options discussed in this section begin with those addressing specific issues raised in four areas of payment: clinical laboratory services, home health services, physicians' services, and hospital services. Options related to more fundamental changes in the health care payment system are then discussed.

Payment for Laboratory Testing

Physicians have financial incentives to order and perform clinical laboratory tests in their offices. The solution to this situation is the development of payment methods with neutral financial incentives for physicians to order diagnostic procedures and to select the least costly settings of test performance.

Option 1: Mandate that Medicare establish a laboratory fee schedule with mandatory assignment for all providers.

Medicare's new fee schedule for laboratory services lowers Medicare's payment for tests, but it may strengthen physicians' financial incentives to conduct laboratory tests in their own offices, even when office tests are more costly than tests sent to independent laboratories.

A fee schedule system that on the one hand requires mandatory assignment of laboratory claims by physicians and on the other allows the physician to bill for services even when they are provided by outside laboratories would give physicians a financial incentive to perform their own laboratory tests only when the tests are less costly to perform in the office than in an outside laboratory.

The fee schedule could be based on the price typically charged by laboratories to physicians. This price is usually competitive, especially in metropolitan areas.

This option would eliminate incentives to perform tests in physicians' offices when they are more costly than sending them out, but it would not necessarily eliminate the financial incentive that physicians have to increase test ordering. If the physician must accept assignment, whether a test is profitable will depend on the difference between the fee allowed by Medicare and the lowest cost at which the physician can provide the service. Careful and constant attention would need to be given to the relationship between prices of tests and efficient production of laboratory services because some tests will continue to be profitable and others may become profitable as new technologies reduce laboratory costs.

Option 2: Mandate that Medicare experiment with other alternatives to the reasonable charge method for clinical laboratory services.

A national fee schedule is just one of the alternatives to the reasonable charge methodology for clinical laboratory services. For example, competitive bidding, negotiated rates of payment, and master contracts have been discussed or implemented by State Medicaid agencies. At present, there is insufficient evidence to assess which of these or other approaches is the most effective approach to purchasing laboratory services for Medicare beneficiaries.

The 1981 Omnibus Budget Reconciliation Act (Public Law 97-35) authorized States to enter into competitive bidding or other similar arrangements to procure laboratory testing for Medicaid populations. A State must demonstrate that laboratory services will be adequate, that selected laboratories will be Medicare-certified, and that no more than 75 percent of the business of the winning laboratory is reimbursed by Medicare and Medicaid. To date, only Nevada has implemented competitive bidding for laboratory services (120).

California is considering development of a "master contract" with terms spelled out and reimbursement rates set. The contract would be offered to any licensed or certified laboratory wishing to provide services to California Medicaid enrollees.

HCFA has had under consideration several demonstration projects to test varying methods of laboratory reimbursement. HCFA plans to test four different procurement approaches through demonstration projects: payment rates established by negotiation with laboratories; fee setting by HCFA without negotiation; competitive bidding with laboratories eligible to provide services as long as they agree to accept the price of the winning bid; and competitive bidding with only winning bidders eligible to provide Medicare testing. Currently, HCFA is awaiting the report of a contractor for design of a competitive bidding methodology (120). It remains to be seen whether the demonstration will actually be undertaken.

The Administration has proposed legislation to authorize the Secretary of Health and Human

Services to purchase Medicare laboratory services by competitive bidding, negotiated payment rates, or exclusive contracts with laboratories (S. 643, H. 2576). Because little is known about the feasibility or impact of these approaches, it seems premature to engage in them on a nonexperimental basis.

Payment for Devices Used in the Home

Medicare reimburses for medical devices used in the home through the durable medical equipment benefit (Part B), the prosthetic devices benefit (Part B), and the home health services benefit (Parts A and B).[18] There are several problems in existing payment methods that may affect the kinds of devices that are used and the prices at which they are offered. Moreover, lack of coordination among these benefit categories creates anomalies in payment for different patients using the same devices.

Option 3: Mandate that Medicare include in per-visit payment limits on home health services the cost of nonroutine equipment and supplies.

Cost-based reimbursement of home health care services creates problems of inflation and inappropriate use of all inputs, including devices. For this reason, Congress has authorized DHHS to limit per-visit rates of reimbursement for routine services to the 75th percentile of the costs of free-standing agencies (those not affiliated with institutions) in similar circumstances. At present, however, the cost of medical equipment, appliances, and supplies that are not routinely furnished in conjunction with patient care visits are not subject to the the limits. This exclusion creates incentives for agencies to "unbundle" their supplies from routine categories to nonroutine categories and to substitute nonroutine equipment, appliances, or supplies for routine nursing or other services whenever possible. Moreover, a home health agency has no incentive to consider price in decisions to purchase nonroutine items.

Integrating nonroutine items into the per-visit limits would eliminate these problems, but it would also increase the already existing incentives for home health agencies to select as clients patients whose need for such items is relatively low. Without a reliable measure of case severity, the potential for such patient selection strategies would probably be high. Therefore, an important priority for research would be development of a patient classification system for home care similar to the DRG system used for hospitals. Even then, there is the question of whether home health agencies are large enough to spread the risk of enrolling patients with high equipment needs across a large enough pool of patients.

Option 4: Encourage Medicare to experiment with alternatives to reasonable charge reimbursement of durable medical equipment (DME).

As with other Part B services, the use of reasonable charge screens—maximum limits on the amount Medicare will pay based on comparative profiles of suppliers' actual charges—for DME probably raises the prices paid for such equipment. Medicare's CPR pricing system for DME creates particular problems in localities with only one or a few suppliers of DME, where a high-priced supplier with at least 25 percent of the locality's market for a particular kind of DME can unilaterally determine the prevailing charge and thus manipulate its payment rate.

Possible alternatives to the CPR pricing system would be national or regional price ceilings and competitive bidding by suppliers. As yet, there is no experience with either of these approaches, so it is unknown how they would affect the availability or prices of DME. Price ceilings based in the beginning on regional or national average prices and adjusted for general inflation over the years would tend to raise prices charged by low-priced suppliers while at the same time lowering those of high-priced suppliers. It might also reduce the access of Medicare beneficiaries, particularly those with low incomes, to DME if assignment rates were to drop as a consequence of the ceilings or if suppliers in high-cost localities were to find it unprofitable to serve Medicare beneficiaries.

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[18] The Medicare program has two parts: Part A, the Hospital Insurance program; and Part B, the Supplementary Medical Insurance plan. Part A's primary purpose is to provide protection against the costs of inpatient hospital care. Other Part A benefits include posthospital extended care services, home health services, and inpatient alcohol detoxification services. Part B services include physician services, outpatient hospital services, outpatient physical therapy, and other ambulatory services and supplies, such as prosthetic devices and durable medical equipment. Part B also covers home health services for those Medicare beneficiaries who have only Part B coverage (345).

Unless this approach were adopted in conjunction with a requirement that suppliers of DME beneficiaries accept assignment or elimination of the 20-percent coinsurance requirement for those accepting assignment, the drop in assignment rates would cause part of the burden of expenditure to shift from Medicare to the beneficiary.

Competitive bidding by suppliers would be most useful in areas with a reasonably large number of potential suppliers. The details of a competitive bidding strategy are important in determining the effect on availability and prices of DME. One approach would be a Medicare requirement that all DME rentals or purchases in a locality be made through the two or three low-bidding suppliers. This approach would probably be successful in driving down prices in the near term, but it has certain drawbacks. First, the bidding would have to be on a product-by-product basis, and it would be impractical to require a beneficiary to use a different supplier for each device bought. Second, the approach could lead to a reduction in the number of suppliers, with consequent increases in prices by remaining suppliers in subsequent years.

The effect of any of these approaches on the price and availability of DME to Medicare beneficiaries could be studied in the context of demonstrations or experiments.

Option 5: Extend Medicare home health benefits to individuals on parenteral or enteral nutrition.

Medicare currently refuses to provide home health care benefits to patients who receive at home total parenteral or enteral nutrition therapy—methods of direct feeding through the bloodstream or gut. Since 1977, Medicare has covered these services as a Part B benefit under prosthetic devices. HCFA has interpreted the prosthetic device benefit as applying only to patients with permanent impairment and as excluding any nursing services. However, as part of training and adjustment for home parenteral and enteral nutrition, nursing services may be required. Patients must receive these services at outpatient departments for nursing services to be reimbursed.

The effect of this regulation is to limit parenteral and enteral nutrition benefits to ambulatory patients with permanent need for the technology. It might be possible to shift patients out of hospitals into home care settings if these restrictions were lifted. However, if home health benefits were extended to patients receiving parenteral and enteral nutrition, the current 20-percent coinsurance rate would no longer apply because home health services (Part A) do not entail coinsurance, and Medicare would bear the full burden of expenditure. To avoid this added cost to Medicare, Congress could authorize DHHS to maintain the relevant equipment and supplies costs as prosthetic devices under Part B, while offering home health benefits under Part A. Patients receiving such services would then be required to copay for the Part B portion but not for the home health services.

Payment for Physicians' Services

Medicare and some other third parties pay for covered physicians' services on a reasonable charge basis. These systems, based as they are on profiles of physicians' charges, tend to have an inflationary effect on physicians' fees because each physician's future payment is tied through the fee screen to currently billed charges. In addition, these systems put a premium on the performance of new procedures for which comparative fee screens have not been established. The physician can charge a high fee for a new procedure and have it reviewed for its reasonableness by a medical review committee composed primarily of practicing physicians. After these fees are established and comparative fee screens are developed, the new procedures remain highly rewarded relative to old procedures.

The Federal Government could adopt for Medicare, Medicaid, and CHAMPUS several options for physician payment to address these problems.

Option 6: Mandate that Federal insurance programs adopt fee schedules that change the relative prices of new v. old procedures and device-bound v. cognitive procedures.

The objective of developing fee schedules that change relative prices is not to discourage the introduction of new devices, but to remove the present financial incentives to select one procedure over another (239).

Implementation of this option would require collection of data on the costs of performing both new and old procedures in order to establish relative prices. It would also require a system for monitoring cost changes in procedures as they diffuse into the practice of medicine (140). Moreover, it is not clear that relative costs are the most appropriate basis for relative prices. Prices should reflect the relative values of procedures, but because of present distortions in the pricing system, it would be difficult to identify differences in these relative values. Hence, setting relative fees would require making judgments about technologies, specialties, and classes of medical care because relative fees affect their use.

How would relative price schedules be affected by voluntary assignment as now exists under Medicare? Voluntary assignment effectively turns a fee schedule into a benefit schedule. A fee schedule limits the amount actually received by the provider, whereas a benefit schedule limits the amount that will be paid by the insurer. Under a fee schedule, the insurer pays only the stated price for a procedure and requires the provider to accept that price as payment in full or not be paid for the service at all. Under Medicaid's mandatory assignment system, a relative price schedule would be a fee schedule. With voluntary assignment, however, the physician could collect the difference between the billed charge and Medicare's payment from the patient, rendering the payment limit a benefit schedule.

To some extent, then, a benefit schedule that paid relatively less for services associated with medical devices and more for cognitive services would result in Medicare patients' paying a greater share of the costs of medical devices. Since people generally use fewer services the greater the level of cost-sharing, the relative use of medical devices would be expected to fall somewhat, but the extent of this effect is unknown.

Option 7: Mandate that Federal insurance programs pay physicians by episode of illness or by person served rather than by procedures or services delivered.

Just as DRG hospital payments provide incentives for hospitals to treat each hospital case in the least costly manner possible with the least costly mix of devices and other inputs, payment for ambulatory physicians' services by the episode or case would offer similar incentives to physicians. In particular, the financial incentives to provide more laboratory tests and other device-bound procedures than is cost effective would be eliminated.

However, this approach would not only eliminate financial incentives to perform specific procedures, since each procedure performed would reduce physicians' net incomes. Whether physicians would actually respond to those financial incentives is unknown. Underprovision of laboratory and other device-bound procedures would be a possibility in some cases and would require monitoring.

This option would also require development of new systems of classifying patients according to medical conditions, complaints, or health status. Otherwise, people with serious conditions and higher use rates might gravitate to certain providers and overburden them financially ("adverse selection"), or some providers might try to attract people considered less costly to treat ("cream-skimming"). At present, the technology of patient classification does not appear to be well developed in the ambulatory care area.

One way to begin implementing this option would be to focus on physicians' services to hospital inpatients. Physicians could be paid a specific fee based on the patient's diagnostic category for the entire hospital stay, rather than for each inpatient visit. This arrangement would provide financial incentives to reduce the number of physician visits to the hospital and, as a consequence, the number of procedures ordered. However, even this limited use of per-episode physician payment would be difficult to implement soon. First, a classification system appropriate to physicians' inputs has not been developed, and the validity of DRGs as a classification system for physicians has not been tested; second, physicians' claims data are not organized in a way that readily allows estimation of the relative use of physician service by inpatients in different diagnoses.

The development of adequate patient classification systems to support payment on a basis other than fee-for-services is expensive, and individual payers have little incentive to support such research. As it has in the past, the Federal Government through HCFA could take the lead in supporting research in this area.

Hospital Payment

Medicare's new DRG payment system establishes a different set of incentives for hospitals. These incentives represent an improvement over the previous cost-based reimbursement system because, unlike the old system, they encourage hospitals to treat each inpatient case in the least costly manner possible. Of course, the DRG system is new and hardly complete; further modifications in its administration can be expected. One such modification with particular relevance to medical devices is the treatment of capital costs. The current system leaves capital costs (depreciation and interest[19]) reimbursed as they are incurred, with no limit on the amount that a hospital can be paid. In conjunction with fixed payment for most other components of inpatient costs, this approach encourages investment in medical equipment and facilities relative to personnel and supplies, which are controlled.

Option 8: Amend the Social Security Act to include payment for capital in DRG payment rates.

The fundamental issue under the newly created Medicare DRG payment system is whether a hospital's capital payment should or should not be subject to some kind of externally imposed limit. The current passthrough reimbursement of capital could continue as a permanent feature of DRG payment. Alternative methods of capital payment that impose limits on reimbursement fall into three categories: 1) those that establish uniform rates of payment across all hospitals (or all within a class); 2) those that establish hospital-specific limits to capital payment; and 3) those that condition payment on approval of capital expenditure projects.

The uniform payment approach would treat all hospitals alike, regardless of their capital or operating expenditures. Uniform payment could be calculated either as a fixed percentage of the DRG price or as a flat rate per bed. Hospital-specific approaches, on the other hand, would take the hospital's capital or operating costs into account in establishing a level of payment, but limit increases in the payment level over time. Thus, for example, capital payments could be limited to a percent of operating costs, so that hospitals with high operating costs would receive a higher capital payment than others; alternatively, the capital payment in any year could be tied to the hospital's actual capital costs (as measured by interest and depreciation) in a base year with adjustments for inflation in subsequent years.

If capital payments were controlled through direct regulation of capital expenditures, only projects approved by a certificate of need (CON) or other designated agency would be recognized by Medicare for capital payment. Approved projects would then be paid on a cost basis. Areawide or statewide annual capital expenditure limits could be used to establish an upper bound on the value of approved projects. The State of New York is currently considering adoption of such a capital expenditure limit (38).

The alternative capital payment methods described above can be evaluated on the basis of four general criteria:

- *Efficiency*—the extent to which the approach promotes the cost-effective use of hospital devices.
- *Equity of access to medical technology*—the extent to which the method promotes equal access among population groups to capital-embodied medical technology.
- *Fairness*—the extent to which the method treats all kinds of hospitals alike, neither

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[19] Capital cost also includes a payment for return on equity, but only to proprietary hospitals.

rewarding nor penalizing hospitals for conditions outside their control.

- *Feasibility*—the extent to which the method is administratively workable and politically acceptable.

As discussed above, a permanent capital cost passthrough under DRG payment violates the efficiency criterion, because it distorts incentives for hospitals to adopt and use capital-embodied devices. However, this approach does well on the other three criteria. Its feasibility has been demonstrated through the years. It is inherently fair because all hospitals face the same rules regarding capital payment. Finally, it poses no barriers to equal access to medical technology, although it does nothing to redress current inequities.

Any of the three controlled payment methods described are more efficient than passthrough capital payment, because the hospital is encouraged to provide its care at the least possible cost. New medical devices would be judged in terms of their impact on total costs, not just on operating costs. Hospitals would be further encouraged to specialize and join in plans for regionalization of health services. However, it is difficult to devise a controlled payment system that is fair to all hospitals. In a uniform payment system, hospitals that in the past have had lower ratios of capital to operating cost would receive more than they had in the past, while those with high ratios would receive less.

A uniform rate of payment would also create a difficult and possibly costly transition if hospitals that have made major investments in recent years or anticipate them in the near future are not to be unduly penalized. The American Hospital Association has recently proposed a uniform capital payment system that would pay each hospital the higher of cost-based reimbursement or a fixed payment rate during a 10-year phase-in period (8). Anderson and Ginsberg have suggested a less generous transition in which "budget neutrality" is maintained by gradually reducing the proportion of the capital payment that is a passthrough (14).

Tying capital payment to the level of capital costs in a base year or to the hospital's operating costs is efficient but may be unfair. This kind of system tends to reward those hospitals who were most capital-intensive in the past, leaving those with low levels of capitalization forever to receive lower payments. Moreover, it would not work well for hospitals requiring major capital expenditures in the early years of implementation. Perhaps for these reasons, support for this approach has been limited to movable equipment, which typically has shorter lifetimes and lower variations in asset values among hospitals.

Hospital capital has two components: the fixed plant and equipment constructed with the facility (new hospital, addition, renovation), and the movable equipment placed in the facility. All capital-embodied medical devices fall into the movable equipment category. The useful lives of movable equipment are usually relatively short (5 to 10 years) and most, but not all, individual equipment purchases are much smaller than the costs of construction. Therefore, it is possible and perhaps even prudent to consider these two classes of capital separately.

Two States, New Jersey and Maryland, have included in their prospective per-case payment systems controls on major movable equipment expenditures (345). In the case of Maryland, the hospital's current value of undepreciated equipment in a base year is built into the controlled hospital rates, with adjustments only for inflation in subsequent years.[20] In New Jersey, the amount allowed for major movable equipment is determined by a blend of the hospital's own current value of undepreciated equipment and the average current value of undepreciated equipment in similar hospitals in the State.

Inclusion of major medical equipment in the DRG payment prices would encourage hospitals to consider the cost of such equipment in decisions about the most appropriate mix of resources. It would probably require a transition phase for new (and newly equipped) hospitals, but the length of the transition could be short due to the short useful lives of the equipment in this category.

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[20] Exceptions can be negotiated with the State's Health Services Cost Review Commission.

It is difficult to predict the effects of direct regulation of capital expenditures through CON or other agencies. Direct regulation can occur with or without statewide or areawide maximum limits on total capital outlays over a given period, and the effects can be expected to differ between the two. Although there has been much discussion in certain States about establishing actual expenditure limits or "pooling" capital, all experience to date has been with CON and section 1122 programs that do not operate with areawide or statewide limits. The experience with capital expenditures regulation in the absence of such limits has been disappointing, with most evaluations concluding that the level of capital expenditures has not been affected (61,63,247,436). Moreover, the distribution of medical technologies among hospitals does not appear to have improved as a result of CON (61).

There is no evidence, either theoretical or empirical, to suggest that the outcome of an annual limit on the level of capital expenditure process would be either efficient or fair (447). A review of the literature on resource allocation decisions by committees revealed that the ultimate outcomes depend on chance and on the composition of the committee and the procedures governing the decisionmaking process (447). Moreover, the kinds of information needed to make informed tradeoffs among competing capital projects is likely to be unavailable, thus leaving the process even more exposed to political solutions.

Regardless of whether or not an areawide limit is applied, direct regulation of capital expenditures is administratively feasible only for large projects —construction and renovation projects and major new services. The current trend toward high thresholds for capital expenditure controls (453) would probably continue, leaving an ever larger proportion of capital-embodied technology to be controlled in some other way.

Systemwide Reforms

All of the options discussed above involve specific adjustments to a payment system that has two fundamental problems: first, the more units of service that are offered, the more the provider is paid, resulting in greater use of the medical services, including devices; and second, the more restrictive one part of the payment system becomes relative to others, the greater is the incentive to shift the settings of service delivery from the more restrictive to the less restrictive ones.

When financial incentives are inconsistent with cost-effective adoption and use, regulatory approaches can be attempted, but they are often unwieldy. For example, the regulatory process of coverage for medical devices creates differential barriers to the introduction of new devices that have little to do with their effectiveness or cost effectiveness. Despite this fact, the sheer size of the task of individually reviewing each medical device for its efficacy and safety (not to mention cost effectiveness) in each potential use as a precondition to coverage argues against the development of such a coverage process. Instead, the difficulties inherent in the coverage process outlined in this chapter seem to support the development of payment methods that create incentives for individual providers or users to make decisions that are consistent with the goals of the Medicare program.

Option 9: Encourage Medicare to move toward payment for medical care (including devices) on a per capita basis.

One remedy for the problems of the current system may be the adoption of per capita payment, in which a set of defined and reasonably comprehensive services is offered in exchange for a fixed premium. Under per capita arrangements, such as those offered by HMOs, all resources used to produce health services are subject to the same constraints, and incentives exist to select the least costly mix of resources.

Per capita payment has two potential problems, however, which suggest that careful assessment be given to this alternative. First, there is the possibility under these plans that people with the greatest need or demand for medical care will enter specific plans and that other plans will selectively enroll low users, leading to unequal cost burdens among alternative plans. Varying the amount of the payment by the age or existing health status of the beneficiary would address this problem, but it is difficult to identify factors that will be associated with greater medical care need. Second, just as fee-for-service medicine gives providers an incentive to provide too many services, providers of services on a per capita basis would have a financial incentive to provide too few. However, competition among plans and the costs of malpractice insurance may limit this risk of underprovision.

4.

Research and Development Policies Related to Medical Devices

Columbus may have been impelled by a desire for spices, but it was the supply of corn which was increased.

—*Kenneth J. Arrow*

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4.

Research and Development Policies Related to Medical Devices

INTRODUCTION

New medical devices arise from a process of research and development (R&D)—purposeful activities requiring the investment of time and other economic resources in the investigation of scientific or technical problems. R&D is frequently classified into three phases:

- *Basic research*—original investigation whose objective is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications in mind (421).
- *Applied research*—investigation whose objective is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met (421).
- *Development*—systematic use of the knowledge or understanding gained from research in the design and development of prototypes and processes (413).

Investment in R&D, particularly in development, is a necessary, but not sufficient, condition for technological progress[1] in medical devices. Some new devices may result from sudden insights, with little developmental work needed; others may require a laborious and slow development phase with high levels of investment. All new devices (or device improvements) need some level of development and possibly research. Yet there are no guarantees that greater investment in R&D will lead to higher levels of technological progress in a field. The productivity of R&D depends to a large extent on the present state of scientific knowledge (413) and to some extent on the existence of a "product champion" (413), but it may also depend on how the R&D is organized: who performs it, who funds it, how funding decisions are made, and the social and economic structure in which it occurs.

The purpose of this chapter is to examine Federal R&D policy as it relates to medical devices.[2] As in other areas of Federal policy, questions of R&D policy transcend the medical devices field. Federal stimulation of industrial R&D through direct subsidies or indirect policies (e.g., tax policy) has been a national concern (67,70). Similarly, Federal support for basic research and training as a long-term national investment in technological change and R&D capacity has been discussed widely in general terms (280) and in terms of biomedical research as a whole (413).

This discussion will concern itself neither with the broad issues of R&D policy nor with public policy instruments that cannot be readily targeted to specific fields such as medical devices (e.g., the use of income and corporate tax incentives to stimulate R&D). It is important to note, however, that global R&D strategies may have an impact on the level, directions, and settings of R&D on medical devices that is as great or greater than the impact of R&D strategies directed specifically at medical devices. (App. G contains an analysis of the impact of recent changes in Federal tax policy on medical devices R&D.)

To address the specific issues pertaining to R&D for medical devices, the chapter first presents data on expenditures for and performance of medical-device-related R&D. The chapter also analyzes sources of support for medical-device-related R&D. The concluding section of the chapter discusses problems that have been identified and policy options to address them.

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[1] Technological progress is defined here as the continual introduction to practice of new and more useful ways of serving human purposes (262).

[2] R&D in the Veterans Administration is discussed in ch. 7.

TRENDS IN MEDICAL DEVICES R&D

For two reasons, it is difficult to identify and quantify R&D activities specifically related to medical devices. First, most basic and some applied research lays the scientific foundation for a wide range of future products and processes, including medical devices, without being specifically attributable to a device or even to a class of devices. Second, the R&D data that are published are either aggregated or classified in a manner that is inconsistent with the definition of medical devices used in this report. The picture of device-related R&D must be sketched from disparate and only partially relevant data sources.

Annual estimates of the level of health-related R&D expenditures in the United States are available from the National Institutes of Health (NIH), but these estimates are not broken down by phase of R&D and are not specific to medical devices. In 1980, health R&D totaled an estimated $7.89 billion, of which 28 percent was performed, and 31 percent was funded, by industry (404).[3]

Annual estimates of R&D conducted by medical device companies are available from the National Science Foundation (NSF) survey of R&D in industrial firms, but their validity as estimates of industrial R&D on medical devices is somewhat limited. The NSF's estimates of company-wide R&D for firms whose primary line of business is one of the five medical device Standard Industrial Classification (SIC) codes[4] overestimate industrial R&D on medical devices to the extent that the medical device companies conduct R&D in other product categories and underestimate it to the extent that R&D for medical devices is conducted by firms classified in other SIC codes. Because many medical devices firms are owned by large multiproduct firms,[5] the balance is likely to be toward underestimation of industrial R&D on medical devices.

NSF's estimates of company-wide expenditures for applied research and development are broken down into general product categories such as "professional and scientific instruments" and "other electrical machinery equipment and supplies." These categories are too broad to allow the extraction of applied research and development expenditures that pertain specifically to medical devices. Basic research expenditures are collected for the company as a whole and are not broken down by product class.

These caveats must be recognized in interpreting table 23, which presents estimates of industrial R&D expenditures aggregated over the five medical devices SIC codes. In the 1974-80 period, industrial R&D expenditures, which include both company and Federal funding, grew at an average annual rate of 16.1 percent in the five medical devices SIC codes, as compared with an annual growth rate of 11.7 percent in industry as a whole (422,424). It is also interesting to note that although R&D expenditures for medical devices are probably underestimated, in 1980, industrial R&D expenditures for firms in the five medical devices SIC codes were equal to 3 percent of the value of such firms' shipments (see table 23); in industry as a whole, R&D expenditures were equal to 2.4 percent of the value of shipments (422,424).

The data suggest that the medical devices industry is relatively R&D-intensive. In 1980, for firms in the five medical devices SIC codes, company-sponsored R&D was equal to 2.9 percent of the value of such firms' shipments; for industry as a whole, company-sponsored R&D expenditures amounted to only 1.6 percent of the value of shipments (422,424). For the rate of company investment in basic research, there is little difference between medical devices firms and industry as a whole. In 1979, firms in the five medical devices SIC codes reported that 3.7 percent of their company-sponsored R&D was basic research, while the figure for industrial firms as a whole was 4.1 percent (422,424).

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[3] The NIH estimates of industrial R&D for health are imprecise and probably underestimated due to limitations of the data on which the estimates were based (449).

[4] The five medical devices SIC codes are: 3693 (X-ray and electromedical equipment), 3841 (surgical and medical instruments), 3842 (surgical appliances and supplies), 3843 (dental equipment and supplies), and 3851 (ophthalmic goods). See ch. 2 for further information on the SIC codes.

[5] Three obvious examples are the General Electric Co., with extensive R&D in medical imaging; E. I. du Pont, with R&D in health-related products; and Johnson & Johnson, Inc., a drug company with several device subsidiaries. (Because Census Bureau data are confidential, it is impossible to state with certainty the severity of the classification problem)

Table 23.—Industrial R&D in Five SIC Medical Devices Codes[a], 1974-80 (dollars in thousands)

Year	Basic research	Percentage of total	Applied research	Percentage of total	Development	Percentage of total	Not identified	Percentage of total	Total	Percentage of shipments
1974...	$ 3,635	2.6%	$35,650	25.1%	$100,361	70.6%	$ 2,434	1.7%	$142,080	2.8%
1975...	NA	NA	NA	NA	NA	NA	NA	NA	168,884	2.9
1976...	6,234	3.1	33,046	16.6	90,957	45.8	68,637	34.5	198,874	3.0
1977...	8,406	3.7	65,994	28.8	154,277	67.5	NA	NA	228,677	2.8
1978...	NA	NA	NA	NA	NA	NA	NA	NA	273,794	3.0
1979...	11,272	3.8	67,968	23.3	188,690	64.7	23,821	8.2	291,751	2.8
1980...	NA	NA	NA	NA	NA	NA	NA	NA	348,707	3.0

NA indicates information not available because of issues of confidentiality.

[a] The five Standard Industrial Classification (SIC) code medical devices categories are:
SIC 3693: X-ray and electromedical equipment
SIC 3841: Surgical and medical instruments
SIC 3842: Surgical appliances and supplies
SIC 3843: Dental equipment and supplies
SIC 3851: Ophthalmic goods

SOURCES: U.S. Department of Commerce, Bureau of Industrial Economics, *1983 U.S. Industrial Outlook*, Washington, DC, January 1983; U.S. National Science Foundation, "Survey of Industrial Research and Development," conducted by the U.S. Bureau of the Census, 1982.

SOURCES OF SUPPORT FOR MEDICAL-DEVICE-RELATED R&D

R&D for medical devices takes place in numerous settings—private companies, hospitals, and university and government laboratories. The sources of support for these activities are highly varied. It is impossible to isolate the sources of funding of medical-device-related R&D performed in academic or government laboratories from those for other health or general R&D, but data are available on the sources of funding of medical devices R&D conducted in industry.[6]

Table 24 shows the sources of support for industrial R&D in the five SIC medical devices codes. The level of support from NIH and other Federal agencies is substantially lower for industrial R&D in these SIC codes than it is for industrial R&D as a whole. In 1980, the Federal Government funded less than 3 percent of the R&D conducted by firms in these SIC codes, compared with 29 percent of R&D conducted by industry as a whole (422).

Federal Support for R&D on Medical Devices

The Federal Government supports over 52 percent of total health R&D, most of it (70 percent) through grants and contracts from NIH (404). Table 25 shows the distribution of R&D grants and contracts awarded by NIH in fiscal year 1982.

Table 24.—Sources of Support for Industrial R&D in Five SIC Medical Devices Codes[a], 1974-80

Year	Total industrial R&D	Federal	Company	Percent change in company-sponsored R&D
	(thousands of dollars)			
1974.....	$142,080	$3,635	$138,445	—
1975.....	168,884	4,878	164,006	18.5%
1976.....	198,874	5,464	193,410	17.9
1977.....	228,677	5,727	222,950	15.3
1978.....	273,794	5,623	269,171	20.7
1979.....	291,751	4,788	286,963	6.6
1980.....	348,707	7,125	341,582	19.0

[a] The five SIC codes are the same as those listed in table 23.

SOURCES: U.S. Department of Commerce, Bureau of Industrial Economics, *1983 U.S. Industrial Outlook*, Washington, DC, January 1983; U.S. National Science Foundation, "Survey of Industrial Research and Development," conducted by the U.S. Bureau of the Census, 1982.

Industry received approximately 6 percent of total NIH grants and contracts for that year. (Of course, these grants and contracts encompass much more than the development of medical devices, including some basic research, drug and biotechnology development, and procurement of items such as research laboratory equipment.)

Despite the small proportion of NIH funds that goes to industry, NIH and other agencies' support for R&D in specific medical device areas is probably sizable in absolute terms. The National Institute for Handicapped Research's Rehabilitation Technology program, for example, administers a $9 million annual program of grants and con-

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[6] The limitations of the NSF industrial R&D survey apply in interpreting these data, however.

Table 25.—R&D Grants and Contracts Awarded by the National Institutes of Health (NIH), Fiscal Year 1982

Performing institution	Total amount (thousands of dollars)	Percentage of total
Domestic institutions	$2,709,248	99%
Nonprofit	2,558,010	94
Higher education	2,025,822	74
Medical schools	1,412,540	52
Government	40,656	1
Federal	2,083	0
Research institutes	470	0
Hospitals	404	0
Other	1,209	0
State and local	38,574	1
Research institutes	1,774	0
Hospitals	26,362	1
Other	10,438	0
Other nonprofit	491,531	18
Research institutes	275,575	10
Hospitals	163,188	6
Other	52,768	2
Profit	151,238	6
Foreign institutions	22,820	1
Total	$2,732,068	100%[a]

[a] Percentage may not sum to 100 because of rounding errors.

SOURCE: U.S. Department of Health and Human Services, National Institutes of Health, Office of Program Planning and Evaluation and the Division of Research Grants, *NIH Data Book 1983*, Washington, DC, June 1983, table 17.

tracts to 18 centers engaged in applied research and development of rehabilitative devices (299). NIH's critical role in supporting the development of renal dialysis technology is described in box G.

A recent analysis of NIH, NSF, and Department of Energy grants and contracts active as of May 1983 revealed that almost $50 million was related to diagnostic imaging (460). This medical imaging R&D was scattered throughout the institutes and agencies and covered a wide assortment of subjects including not only development or refinement of new imaging devices, but the use of imaging techniques to enhance understanding of disease processes. A high proportion of these grants went to academic and other nonprofit institutions, and therefore supplemented the R&D on medical imaging conducted by industry. NIH funding in the medical imaging area has, in retrospect, had important impacts on the later development of commercial imaging devices. Box H presents the history of Federal funding for research on nuclear magnetic resonance (NMR) imaging.

Private Sources of Funds for R&D on Medical Devices

How do medical device firms go about financing the R&D that is not supported by direct grants and contracts? Firms have two potential sources of financing: retained earnings and the financial capital markets. If funds are sought from external sources, they may be generated either through debt or equity instruments. Tables 26, 27, and 28 present data on the sources of financial capital to firms in three Internal Revenue Service (IRS) industry categories:

- optical, medical, and ophthalmic goods (IRS 3845);
- other electrical (including but not limited to X-ray and electromedical devices) (IRS 3698); and
- all manufacturing (IRS 40).

These industry classifications include a substantial number of firms not engaged in the production of medical devices, and the data pertain to

Box G.—Federal Support for Renal Dialysis R&D[1]

The research activities of the Federal Government have played an important part in the development of knowledge on the causes and treatment of end-stage renal disease (ESRD). The National Institutes of Health (NIH) funded early work on maintenance dialysis and supported research on transplantation as well. In 1982, the total amount spent by NIH on kidney-related research was estimated at about $90 million (269). This might be compared with the approximately $73 million spent by NIH on kidney and urinary tract diseases in 1979 and the $47 million spent in the area in 1976 (396). The Veterans Administration and the Public Health Service have also provided resources for the demonstration of maintenance dialysis therapy. The research support continues today, but some difficult policy issues are evident.

The contribution to dialysis treatment of this Federal investment is significant. NIH has contributed to the development of a number of innovations, including the following (269):

- development of hollow fiber dialyzers,
- enhancement of efficiency of flat-plate dialyzers,
- introduction of "single-needle" dialyzers,
- determination of protein levels for diets for dialysis patients,
- establishment of national registry of patients on dialysis (responsibility later assumed by the Health Care Financing Administration),
- development of specific absorbents for uremic wastes,
- development of wearable artificial kidney for self-treatment,
- improvement in prevention and treatment of chronic bone pain and bone fractures in patients,
- development of treatment measures for chronic anemia in patients, and
- development of concept of hemofiltration.

An examination of trends in funding, however, suggests that these direct contributions are likely to decline. Overall spending for the Chronic Renal Disease Program, a subdivision within the National Institute of Arthritis, Diabetes, and Kidney Diseases' Kidney and Urologic Diseases Program fell roughly 31 percent between 1979 and 1981, after adjustment for inflation. Research in the area of maintenance therapies, which included applied research on hemodialysis, peritoneal dialysis, hemofiltration, and other aspects of therapy, fell by 68 percent over the period. Furthermore, within NIH as a whole, maintenance therapies took up only about 6 percent of the ESRD-related research (461).

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[1] Based on a case study prepared for OTA by Romeo (260).

the financing of *all* activities in these fields, not just the financing of R&D and innovation. Consequently, the interpretation must proceed with caution.

Table 26 shows that in 1980, external equity became a very important source of financing for small firms in the optical, medical, and ophthalmic goods category. Retained earnings have consistently been less important to firms in this category than they are to manufacturing firms as a whole. The shift by small firms in the optical, medical, and ophthalmic goods category toward external equity may be the result of the infusion of large amounts of venture capital into new companies in this area in 1979. Notice also that small optical, medical, and ophthalmic goods companies depend to a greater extent on all forms of external financing than do large firms in the same industry.

The role of venture capital in financing innovation in general and new medical devices in particular has increased dramatically since 1978. Venture capitalists are investors who specialize in providing financial capital to small and, sometimes, new firms. From 1969 to 1977, the total venture capital pool in the United States remained virtually unchanged, at the level of about $2.5 billion to $3 billion (190). Since then, however, the total venture capital pool has increased sharply, reaching between $3.5 billion and $4 billion in 1979 (441), $5.8 billion in 1981 (442), and an estimated $7.5 billion as of December 1982 (440).

Box H.—Federal Funding of Research on Nuclear Magnetic Resonance (NMR) Imaging[1]

Government policies related to funding of medical device research and development (R&D) by universities and manufacturers can have important impacts on the evolution of technology and the shape of particular device industries. The history of Government funding of NMR imaging research in the United States reflects these impacts.

NMR imaging is an exciting new diagnostic imaging modality that has captured the interest of the medical profession. It has many desirable attributes, including the use of radiowaves and powerful magnetic fields rather than ionizing radiation. It also offers excellent tissue contrast without the need for injection of potentially toxic contrast agents and allows visualization of areas such as the posterior fossa, brain stem, and spinal cord, which are not well seen with other imaging techniques. Finally, the technique offers the *possibility* of detecting diseases at earlier stages than is currently possible and of permitting accurate pathologic diagnoses to be made noninvasively.

NMR also has disadvantages. NMR imagers are expensive and logistically difficult to install. They may also require more physician time in performance of patient examinations than do computed tomography (CT) or other imaging techniques. Moreover, at this time, the exact role of NMR imaging in clinical medicine, particularly its efficacy compared to other imaging modalities, has yet to be defined.

Over the past decade, the National Institutes of Health (NIH) has supported research relating to NMR imaging, biomedical applications of NMR parameters, and biomedical applications of NMR spectroscopy. Although NIH has provided some funds for development and use of software and ancillary hardware, it has not provided, and does not plan to provide, support to clinical or research institutions to be used either to develop or purchase NMR imaging machines for use in human imaging.

NIH has had an active intramural program of research involving applications of NMR for many years. Over the past 6 years, Dr. David Hoult, a physicist and electronics engineer, has conducted research focusing on NMR imaging instrumentation and techniques. Dr. Robert Balaban has been studying physiological applications of phosphorus, sodium, and nitrogen NMR spectroscopy for the past 3½ years. Also, a research group has been formed by Dr. Charles Meyers of the National Cancer Institute (NCI) to explore the use of NMR in the study of the metabolism of both normal and cancer cells as well as the effect of various drugs on cellular metabolism. The group will also be exploring possible applications of NMR to the study of tumorigenesis (62).

Using funds contributed by several institutes, NIH has purchased a whole-body NMR imaging system on which it will perform clinical studies including investigations of demyelinating disease, the effects of chemotherapy and radiation therapy on NMR parameters, and whether NMR can be used to predict patients' responses to chemotherapy and radiation therapy.

NIH has also engaged in active extramural support of NMR imaging. Although a few of the NMR-related extramural grants have been funded by the National Heart, Lung, and Blood Institute (NHLBI) and other institutes, most of them have been funded by NCI. The first extramural NCI grant related to NMR imaging was awarded to Paul Lauterbur at the State University of New York-Stony Brook in 1973 after publication of a landmark article on NMR (191). The award was made to help Lauterbur further develop his techniques of NMR imaging and investigate its application to cancer research. His initial funding of approximately $100,000 per year for 3 years has been renewed at an approximately constant level, without interruption, since 1973. Lauterbur also received a grant from NHLBI in 1975 related to the use of NMR imaging to study blood flow and an additional $200,000 per year from that institute since 1978. NIH also supported early work on NMR measurements of surgically excised human tumors (76,77) and tumors in mice and rats (144,152), as well as on the imaging of tumors in live animals (75).

NIH is currently funding approximately $2 million of research relating to NMR imaging or in vivo spectroscopy in at least 10 different institutions (460). The Department of Energy has awarded an additional $1.8 million for NMR-related research (460). In October 1982, the Diagnostic Imaging Research

Branch of NCI announced a solicitation of proposals for the performance of studies: 1) to explore and define the current and potential usefulness of present-day NMR imaging systems in clinical applications; 2) to establish optimal imaging conditions for NMR use in specific clinical problems; and 3) to carry out comparative performance and evaluation studies to determine the capabilities and limitations of NMR imaging systems in comparison with other modalities. Announcement of awards, which originally was to take place in June 1983, occurred in spring 1984 (250).

NIH is also planning to issue a Request for Applications for grants to study the physical, chemical, and biological bases for the measurements used in NMR imaging. Although a 3-year program with up to $1 million in grants in the first year is being considered, to date funds have not been approved (250). NIH is also considering the possibility of funding a small number of training fellowships in NMR (250).

The National Science Foundation (NSF) supported a $309,000 pioneering research project in NMR imaging at the University of California, Berkeley, through its Research Applications Directorate (Instrumentation Technology Program) during 1977 through 1979, but currently has no programs that support research in NMR imaging per se. In the most recent Small Business Innovation Research program solicitation of NSF, research proposals pertaining to the application of superconductivity to electronically oriented industries, improved NMR probes, and new procedures for NMR data display have been particularly encouraged.

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[1] Based on a case study prepared for OTA by Steinberg and Cohen (291).

Table 26.—Sources of Financial Capital to Firms in IRS Category 3845: Optical, Medical, and Ophthalmic Goods, 1976-80

	Asset size class (000s)	
Ratio	$1-$5,000	$5,000+
External equity to assets		
1980	0.38	0.18
1979	0.16	0.19
1978	0.23	0.18
1977	0.24	0.20
1976	0.26	0.23
Retained earnings to assets		
1980	0.08	0.35
1979	0.16	0.37
1978	0.14	0.39
1977	0.21	0.40
1976	0.26	0.40
Long-term debt to assets		
1980	0.14	0.13
1979	0.27	0.17
1978	0.20	0.16
1977	0.20	0.14
1976	0.12	0.13
Short-term debt to assets		
1980	0.20	0.17
1979	0.24	0.13
1978	0.22	0.16
1977	0.17	0.17
1976	0.20	0.15
Trade debt to assets		
1980	0.18	0.17
1979	0.13	0.15
1978	0.17	0.12
1977	0.13	0.09
1976	0.18	0.09

SOURCE: U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1976-80, as cited in (26).

Variability in the amount of venture capital in the United States is influenced by many factors, including sensitivity to general variables in the overall economy (e.g., interest rates and inflation), changes in capital gains tax laws, and changes in pension fund investment rules.

Recent changes have led to a resurgence in the United States in the supply of venture capital. Especially important to the supply of venture capital have been decreases in the rate at which long-term capital gains are taxed. In 1978, the rate of taxation was reduced substantially; more recently,

Table 27.—Sources of Financial Capital to Firms in IRS Category 3698: Other Electrical, 1976-80

	Asset size class (000s)			
Ratio	$1-$5,000	$5,000-$25,000	$25,000-$100,000	$100,000+
External equity to assets				
1980	0.16	0.18	0.14	0.09
1979	0.12	0.14	0.15	0.10
1978	0.20	0.17	0.15	0.12
1977	0.22	0.18	0.14	0.13
1976	0.16	0.23	0.19	0.13
Retained earnings to assets				
1980	0.16	0.33	0.48	0.22
1979	0.27	0.39	0.42	0.23
1978	0.22	0.37	0.48	0.25
1977	0.19	0.40	0.47	0.25
1976	0.29	0.35	0.45	0.25
Long-term debt to assets				
1980	0.18	0.14	0.13	0.27
1979	0.13	0.13	0.17	0.28
1978	0.14	0.14	0.13	0.27
1977	0.14	0.12	0.13	0.24
1976	0.11	0.13	0.15	0.28
Short-term debt to assets				
1980	0.32	0.21	0.15	0.30
1979	0.25	0.18	0.16	0.27
1978	0.22	0.19	0.16	0.25
1977	0.22	0.18	0.16	0.26
1976	0.22	0.18	0.13	0.23
Trade debt to assets				
1980	0.19	0.16	0.10	0.12
1979	0.19	0.14	0.10	0.12
1978	0.20	0.13	0.10	0.13
1977	0.21	0.12	0.10	0.12
1976	0.20	0.11	0.09	0.11

SOURCE: U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income* for years 1976-80, as cited in (26).

the Economic Recovery Act of 1981 established the long-term capital gains tax rate at 20 percent for individuals and 28 percent for corporations, making venture investments more attractive than they were under the pre-1978 rate of 49 percent. Also, in 1979, pension fund regulations of the Employee Retirement Income Security Act were interpreted as allowing some pension fund money to flow into venture capital investments.

The results of these changes are evident in data presented in table 29, which shows capital commitments to private venture capital funds for the years 1978 to 1982. Not only have the total annual outlays of venture capital funds increased as a whole, but also the amount available from pension funds has grown dramatically since 1979: in 1982, pension funds represented one-third of the new capital commitments to private venture capital firms (443).

In 1981, venture capital investments in medical and health-related products and services constituted about 6 percent of investments made in organized venture capital markets (26). Table 30 shows the 1982 distribution of venture capital investments by stage of investment in four product categories: medical imaging, other medical products, industrial products, and electronics.

The two medical devices categories—medical imaging and other medical products—show a relatively high proportion of investments in early stages, although in medical devices, as in other fields, the organized venture capital market appears to invest negligible amounts at the earliest (seed money) stage of development. The relatively important role of venture capital firms in financing the startup of new medical device firms suggests that investors have been more likely to take greater risks in this field than they have in other

Table 28.—Sources of Financial Capital to Firms in IRS Category 40: All Manufacturing, 1976-80

	Asset size class (000s)			
Ratio	$1-$500	$5,000-$25,000	$25,000-$100,000	$100,000+
External equity to assets				
1980	0.13	0.13	0.16	0.16
1979	0.13	0.12	0.16	0.16
1978	0.14	0.13	0.17	0.17
1977	0.18	0.15	0.18	0.17
1976	0.16	0.16	0.19	0.18
Retained earnings to assets				
1980	0.29	0.33	0.33	0.28
1979	0.30	0.34	0.33	0.29
1978	0.28	0.35	0.34	0.30
1977	0.28	0.36	0.34	0.30
1976	0.29	0.35	0.34	0.28
Long-term debt to assets				
1980	0.18	0.18	0.28	0.25
1979	0.18	0.18	0.20	0.24
1978	0.17	0.16	0.20	0.24
1977	0.17	0.17	0.21	0.25
1976	0.16	0.17	0.20	0.26
Short-term debt to assets				
1980	0.21	0.21	0.19	0.19
1979	0.21	0.21	0.19	0.18
1978	0.21	0.21	0.18	0.17
1977	0.21	0.19	0.17	0.16
1976	0.20	0.19	0.17	0.15
Trade debt to assets				
1980	0.18	0.15	0.12	0.12
1979	0.19	0.15	0.12	0.13
1978	0.19	0.15	0.12	0.12
1977	0.18	0.14	0.11	0.12
1976	0.19	0.13	0.10	0.12

SOURCE: U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1976-80, as cited in (26).

Table 29.—Capital Commitments to Independent Private Venture Capital Funds, 1979–82

	1978	1979	1980	1981	1982
Total capital committed (dollars in millions):					
Corporations	$ 22	$ 28	$127	$142	$ 175
Endowments and foundations	19	17	92	102	96
Foreign investors	38	26	55	90	188
Individuals and families	70	39	102	201	290
Insurance companies	35	7	88	132	200
Pension funds	32	53	197	200	474
Total	$216	$170	$661	$867	$1,423
Percentage of total capital committed:					
Corporations	10%	17%	19%	17%	12%
Endowments and foundations	9	10	14	12	7
Foreign investors	18	15	8	10	13
Individuals and families	32	23	16	23	21
Insurance companies	16	4	13	15	14
Pension funds	15	31	30	23	33
Total	100%	100%	100%	100%	100%

SOURCE: Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field," contract report prepared for the Office of Technology Assessment, August 1983. See app. F for a description of the Venture Economics database from which these data were derived.

Table 30.—Percentage of Types of Venture Capital Financing in Medical Devices and Other Fields, 1982[a]

Type of financing	Medical imaging	Other medical products	Industrial products	Electronics
Seed money	0%	1%	1%	1%
Startup and first stage	57	56	29	35
Expansion	43	38	37	58
Leveraged buyouts and acquisitions	0	1	27	1
Other	0	4	6	5

[a] See app. F for a description of the Venture Economics database from which this table is derived.

SOURCE: Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field," contract report prepared for the Office of Technology Assessment, August 1983.

fields, even in a traditionally high-technology product category such as electronics. Yet, these data also suggest that small and new firms seeking seed money must frequently look to their owners' and friends' contributions of both time and money. See box I for an example.

THE SMALL BUSINESS INNOVATION RESEARCH PROGRAM

The Small Business Innovation Development Act (Public Law 97-219), enacted into law in 1982, requires each Federal agency whose extramural R&D obligations exceed $100 million to set aside a small percentage[7] for R&D grants or contracts with small businesses. NIH's Small Business Innovation Research (SBIR) budget amounted to $5.6 million in fiscal year 1983 and $8.2 million in fiscal year 1984.[8] The awards are made in three phases: Phase I involves small awards of 6 months' duration for proving the scientific and technical feasibility of new ideas; Phase II involves further development of these ideas with the addition of a plan to acquire non-Federal venture capital in the subsequent phase; and Phase III involves only non-Federal capital committed to pursuit of commercial applications (but Federal involvement may be in the form of agreements to purchase products).

Each agency may determine the categories of projects within its SBIR program and has control over the size of the maximum award in each phase, the amount of sharing of R&D expenses required of awardees, and the methods and procedures used to solicit and select among proposals. Because the SBIR program is specifically targeted to ideas with commercial promise, the grant awards are generally skewed toward applied research and development and away from basic research.

The NIH SBIR program made its first Phase I awards in October 1983 in the form of grants of $50,000 in total costs or less. NIH required grantees to commit to sharing in the costs of the research and will pay no profit or fee in addition to costs. An analysis by OTA of NIH SBIR grant applications and awards revealed that an estimated 42 percent of the SBIR applications responding to the first solicitation were for medical devices (see table 31). No significant differences were found in the ratio of awards to proposals between medical devices and other types of research.

It is premature to evaluate the effectiveness of the SBIR program on small business innovation in medical devices. Although it is clear that there has been a reallocation of research dollars from other R&D programs within NIH to the SBIR initiative, it is unknown to what extent the dollars have been shifted from research funds that would have gone to academic and nonprofit institutions or from research funds that would have gone to industry anyway. Furthermore, if the shift occurred within industry, it is unknown at this time to what extent it represents a net transfer of R&D funds from large firms to small firms or simply a net redistribution of Federal funds among small firms.

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[7] The percentage increases from 0.2 in fiscal year 1983 to 1.25 within 4 years.

[8] NIH actually expended $7.3 million in fiscal year 1983 (425).

Box I.—Financing New Devices: Metatech Corp.[1]

After having spent 35 years with major companies in the pharmaceutical industry in jobs ranging from bench chemist to executive vice-president, I decided in 1978, as so many others had decided before me, that it was now time to become my own boss and to do only those things that I wanted to do. Accordingly, I established Metatech Corp. with the not too modest or restrictive mission "to develop products based on high technology." Because of my background, it was probably inevitable that most of my interests would be in the medically related field, although we do have several products not related to medicine. . . .

I decided that during the initial phase of company development I would not build up an internal research staff. The first dollars spent by a company for research are usually devoted entirely to new and creative projects. However, as a company grows, more and more money is spent protecting what has already been developed. In addition, a research staff that must be kept busy has been built. It sometimes happens that when a project is finished by a group of researchers, the next problem is not the one that the staff is best qualified to solve. Since research staffs are never terminated, the alternative is to allow the existing staff to continue work along lines of their own interests, and other specialists are hired to enter new areas. . . .

In my own experiences, I had had contacts with research and development groups throughout the world, so I thought I knew where the best talent existed to solve any problem. To meet my own requirements, then, without building up a staff I decided to do all my work through outside contracts. Thus, when a problem was solved, the research group no longer existed as an overhead for the company. This procedure has worked very well. Projects have been worked on in England, Israel, Japan, West Germany, and Belgium, as well as here at home. . . .

I had set a time limit of 5 years during which to develop a line of products that could then be sold through any of the channels mentioned previously. How successful has this effort been? We now have 21 products available for promotion and sale. All of them meet the criteria that I established originally. Eleven patents have already issued, and we have 16 applications pending. A long list of potential products awaits future funding. . . .

I have not mentioned the first hurdle that an inventor or entrepreneur must overcome, namely financial support. Partly from choice, partly from necessity I financed Metatech with my own money. At the beginning,I made a few half-hearted attempts to interest outside investors in my company. However, I soon found out that venture capitalists were really not interested in venturing. I had no sales or profits, so there was a risk connected with the operation. I therefore decided to finance my own work, to make my own mistakes in private, but also to have the total freedom to do anything I wanted to do. After having developed some 20 products, I tried again. In March of 1983, I received the investment capital to establish the organization necessary to market the products. . . .

Occasionally, I think back to the days when I could work a normal 12-hour day and depend on someone else to do important things like making coffee. These occasions occur only rarely, and do not last long. Two major hurdles have been overcome—financing and development of products—and preliminary sales contacts and some sales have been made. I might even start to build an internal research organization.

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[1] Excerpted from a paper prepared for OTA by Carney (54).

Table 31.—Analysis of Applications for Small Business Innovation Research (SBIR) Grants, National Institutes of Health, 1983[a]

	Biotechnology applications[b]	Medical devices applications[c]	All other applications[d]
Percentage of total grant applications	6%	42%	52%
Percentage of applications receiving awards	21%	23%	18%

[a] See app. E for estimation methods.
[b] Proposals for R&D on medical devices and other technologies using biotechnology.
[c] Proposals for R&D on medical devices not using biotechnology.
[d] Proposals for R&D on technologies that neither involve the use of biotechnology nor are medical devices.

SOURCE: Office of Technology Assessment.

Implementation of the SBIR program may also affect the productivity of the SBIR program in stimulating development of new medical devices. One issue is whether or not the program stimulates those with the best ideas from a commercial perspective to submit grants. It is interesting to note that in fiscal year 1983, the Department of Health and Human Services (DHHS) (mainly NIH) had the lowest ratio of proposals to awards—six to one—of all Federal agencies. The average ratio of proposals to awards for Government as a whole was 11 to 1 (425). Implementation strategies, including the choice of topics included in the Public Health Service solicitation, the methods used to distribute information on the SBIR program to small businesses, and policies regarding cost-sharing are likely to have influenced the proposal rates.

FEDERAL SUPPORT FOR ORPHAN DEVICES

The Federal Government has recently been charged with the responsibility of identifying and promoting "orphan products," including both drugs and medical devices. The Orphan Drug Act (1983, Public Law 97-414) defines orphan products as drugs and devices for rare diseases or conditions. A rare disease or condition is further defined in the act as one that occurs so infrequently that there is no reasonable expectation that the cost of developing or making the product for such a condition can be recovered from sales of the device.

In the case of drugs, the 1983 act authorizes the Secretary of Health and Human Services to provide four kinds of support for those that have been found to be orphans:

- a 50-percent tax credit on all clinical testing expenses associated with the drug,
- award of an exclusive 7-year right to market a drug that is unpatentable (through the new drug approval authority of the Food and Drug Administration (FDA)),
- technical assistance in the development of clinical testing protocols, and
- award of grants and contracts for clinical testing expenses associated with an orphan drug. (FDA budgeted $500,000 for this function in fiscal year 1983 and $1 million in 1984 (116).)

These benefits are not available to devices.

The 1983 law also established an Orphan Products Board, with responsibility to "promote the development of drugs and devices for rare diseases or conditions . . .," but its specific functions relate to drugs alone. Thus, the support of orphan devices under the new law is largely a conception rather than a reality. Recently, however, NIH has become active in supporting R&D on orphan devices. For example, the National Institute of Neurological and Communicative Disorders and Stroke issued a request early in 1984 for proposals to develop orphan products including drugs, biologicals, and devices (403).

The definition of an orphan device as stated in the 1983 law and in most discussions of the issue

(115,405) is inadequate because it fails to differentiate between products that are prohibitively costly but not particularly valuable from those that are both costly and valuable. Ideally, a device should be considered an orphan when it can be shown to be:

- very valuable to potential users, particularly in relation to the cost of development, production, and distribution: and
- so costly to develop, produce, and distribute that it would be impossible or inequitable to expect potential users to pay a price that would allow producers to recover these costs.

To take an extreme example, a lifesaving device whose cost per patient is $100,000 would be likely to meet the ideal criteria for an orphan device, whereas a $100,000 per-patient device that improves the quality of life a bit for only a fraction of those who use it probably would not.

Products for rare diseases or conditions frequently (but *not always*) meet the aforementioned criteria for an orphan device, because a large part of the cost of R&D and marketing is fixed regardless of the number of units actually sold. With fewer potential users over which these costs can be spread, the price at which the device would have to be sold is likely to be prohibitive. However, a product for a rare disease that is not particularly valuable to users in relation to its costs would not meet the two criteria above, though it would fall into the definition in the act.

There may also be products for relatively common diseases whose costs are still high relative to patients' abilities to pay for them. See box J for a discussion of wheelchairs.

Health insurance, developed as a response to the disparity between the cost of services and patients' abilities to pay for them, complicates matters even further. Third-party payment, which spreads the burden of payment across a broad pool of individuals, is a mechanism for rendering previously orphaned services and products affordable. Indeed, because health insurance generally reduces patients' out-of-pocket costs for health care services, a device whose cost would normally be prohibitive may have an effective price well below that level. For example, coronary artery bypass graft surgery and its related care were estimated to cost approximately $15,000 to $20,000 in 1981 (454). Third parties have paid for a very large share of these costs, and in 1982, approximately 170,000 bypass operations were performed (401).

Health insurance also forces a redefinition of the market, because insurers' decisions about the coverage of a device and, if covered, the appropriate level of payment become major determinants of patients' and providers' abilities to pay for it. If a service is not covered by health insurance, it may be orphaned; covered and paid for generously, it is not.

Thus, the definition of an orphan device is inextricably linked to the policies of third-party payers. Whereas drugs, particularly those prescribed for use outside of hospitals and other institutions, are poorly covered by health insurance plans (insurance paid only 26 percent of total U.S. expenditures for outpatient prescribed medicines in 1977 (180)), and may therefore occasionally be prohibitively costly to potential users, expensive devices are, with exceptions, in a more favorable position. Devices used for diagnosis or therapy in hospitals, physicians offices, and the home are generally covered by public and private health insurers.

Coinsurance requirements usually follow those for other services provided in the same setting. For example, diagnostic laboratory tests provided as part of the physician's office visit typically have the same coinsurance rate (say, 20 percent) as is applied to the physician's own service.

An example of the difference that insurance payment can make in the definition of an orphan is the recent characterization of an immunoassay test for testicular cancer as an orphan by FDA (205). The test is considered an orphan device because the prevalence of testicular cancer in the United States is less than 200,000 (116). Yet this test will probably be covered by third-party payers as a diagnostic service; so it is questionable whether it actually requires special development assistance.[9]

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[9] FDA has not provided substantial assistance to the developers of the test (116).

Box J.—The Wheelchair: An Orphan Device?[1]

Wheelchairs fall into four broad categories: general-purpose manual wheelchairs, power wheelchairs, manual sports wheelchairs, and power alternatives (other motorized vehicles not shaped like a chair). The term "wheelchair" refers here to all four types of equipment.

OTA reported in 1982 that there were about 9 million Americans with lower extremities missing, paralyzed, or impaired (352). Of those people, approximately 1,168,000 (1 American in 200) used wheelchairs. Users in 1977 included 650,000 noninstitutionalized persons (367) and an additional 518,000 residents of nursing homes. The number of nursing home users is expected to grow to 584,000 by 1985, an annual growth rate of 1.5 percent (251).

Although the total size of the wheelchair market is large, the needs of potential users in terms of function and design are highly varied. A 1983 market study by Invacare estimated that the home-care market accounts for 30 percent of the $125.7 million total wheelchair market. (Home-care chairs tend to be manual, fairly standard models for people with limited mobility.) Another 30 percent of the market was attributed to institutions, including hospitals, nursing homes, and rehabilitation centers. (Institutional wheelchairs are also standard, manual chairs used almost exclusively for transport within the institution.) The remaining 40 percent was attributed to rehabilitative care, for active and acute users who are neither home-bound nor institutionalized. (Rehabilitative chairs may be from any of the four basic categories and cover a wide range of customization and cost.)

Over half of all wheelchair purchases are at least partially paid for by government sources. In 1976, 11 percent of purchases were reportedly paid for by the Veterans Administration (213). An estimated 90 to 95 percent of all wheelchair purchases are at least partially funded by third parties (Government or private insurer); only 5 percent are paid totally by the user (214).

Blue Cross of Massachusetts, the largest private insurer in that State, illustrates the impact of insurance payment decisions on the market for wheelchairs. Insurance coverage of wheelchairs depends first on whether the patient's policy covers durable medical equipment. If it does, reimbursement is usually for 80 percent of the reasonable charge. However, Blue Cross will pay only for the least costly wheelchair that meets the user's physical needs. For a new, more costly wheelchair to be covered, it must have a unique feature of *medical* benefit not available on a less costly model. Depending on the policy, purchase of an electric wheelchair is covered up to $2,711; power alternatives are covered up to $2,700. New products are reviewed for coverage by the Medical Review Board. A Physician Advisory Panel may be consulted in cases where the medical benefits of a new product to an expensive new wheelchair with potential usefulness to a small fraction of the market will actually be reimbursed at a level sufficient to make it affordable to those who would benefit from it.

Thus, it appears that although the overall market for wheelchairs is large, the disparate needs of users and the limitations on payment rates may substantially reduce the effective market for new, more expensive designs. More research would be needed to determine whether wheelchairs constitute a class of orphan devices.

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[1] Based on a case study prepared for OTA by Shepard and Karon (282).

Thus, while insurance coverage for the use of diagnostic and therapeutic devices is not complete, it is generally much higher than for outpatient drugs. Exceptions to this general rule are:

- preventive devices (e.g., screening tests, home self-testing kits), which are less frequently covered under health insurance plans;
- rehabilitative devices, which are often poorly covered under private and public third-party payment plans (352); and
- devices subject to restrictive third-party payment limits (e.g., some hospital devices under Medicare's per-case pricing for inpatient hospital care).

Even in these categories, however, most devices will not meet the ideal definition of an orphan. If they can be developed and distributed at a sufficiently low price, a large enough market may still exist despite poor coverage by third parties.

STATE AND LOCAL INITIATIVES RELATED TO R&D FOR MEDICAL DEVICES

States have increasingly looked to R&D-intensive industries such as medical devices for economic development opportunities. A recent census of State government initiatives for high-technology development conducted by OTA identified 38 programs in 22 States with "dedicated" programs of high-technology development (353). In addition, OTA identified 15 "high-technology education" initiatives, undertaken in conjunction with State universities and dedicated to providing to inventors and entrepreneurs the skills they need to create firms that will develop or commercialize emerging technologies. Only a few of these programs actually provided product development assistance or laboratory or office space for new and growing businesses.

Perhaps the program most directly relevant to medical devices is the Health-Care Instrument and Device Institute (HIDI) at the State University of New York at Buffalo, which has been designated by the State of New York as a State-supported center to facilitate direct interface between academic institutions and the needs of industry (see box K). Although the HIDI program has several missions, an important one is to put into practice ideas generated by inventors in the university community (113).

Another popular initiative is the establishment of a research or science park on or adjacent to a university campus. These parks are often encouraged by State or local tax incentives, but many universities have also seen the advantage of encouraging this type of development. In general, these and other university-based initiatives are seen as a way of providing consulting opportunities for faculty, employment opportunities for students, and enhanced research funding for the university. Rensselaer Polytechnic Institute, for example, has provided incubator space for entrepreneurs who need assistance to start a busi-

Box K.—The Health-Care Instrument and Device Institute (HIDI)[1]

As part of its advanced technology program, the State of New York has recently designated and funded the School of Medicine, State University of New York (SUNY) at Buffalo as a center for health care technology. HIDI at SUNY-Buffalo was officially designated in January 1984 as a center to facilitate the direct interface between academic institutes and the needs of industry. The State of New York will provide dollar-for-dollar matching funds with other sources up to a maximum of $1 million per year.

HIDI has a core staff of seven at present and is further supported by the scientists and physicians at SUNY-Buffalo and the Roswell Park Memorial Institute.

One of HIDI's missions is to put into practice ideas generated by inventors in health care technology. Most of the inventions, though not all, are expected to be drawn from the university community. Special incentives are used to encourage faculty to submit their ideas to HIDI for potential development. In return, faculty members may receive increased compensation.

HIDI is generally involved in development only to the point of demonstrating technical feasibility and clinical applicability. Then, the patents and technical know-how are sold to firms on an exclusive basis. HIDI will also undertake proprietary R&D for industry on projects that are initiated by sponsors and will generally receive royalties for any inventions that arise.

The ultimate goal of HIDI is to be self-sustaining, with subsidies from New York State gradually tapering off and being replaced by self-sustained income from sales to and contracts with industry.

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[1] Based on an article by Anbar (13).

ness (354). Several other universities also provide incubator space for students, including Georgia Tech, Carnegie-Mellon University, Massachusetts Institute of Technology, and the University of Missouri (which also provides commercialization assistance to students.) While some of these centers also assist qualifying small businesses, their major emphasis is on the enterprising student (354).

University-based programs such as these have been criticized for drawing faculty away from the conduct of more basic research in favor of applied research and development. There is also the related issue of maintaining free and open communication within the research community. Successful commercialization requires shielding a potential product from a firm's competitors, as well as obtaining proprietary rights to the invention. To some extent, these requirements conflict with the ideal of freedom of expression in academic environments. Nor has it been documented that the resources provided by university-based centers are addressing the specific barriers to commercialization faced by small or new firms. Since most of these projects are relatively new, it is not possible at this time to evaluate their effects either on innovation or on the quality and quantity of basic research.

DISCUSSION AND POLICY OPTIONS

Is the current level of Federal and industry support for R&D related to medical devices adequate? Federal support for industrial R&D can be viewed as supplementing private firms' activities in ways that advance the public good. Federal support is justified when private firms are not likely to engage in as much R&D as is socially desirable.

Basic research has long been recognized as being particularly subject to underfunding by private firms (56,228,230). To be efficient, basic research should embody as few constraints as possible on research directions and be subject to wide disclosure of research results. These conditions conflict with the ability of private firms to reap the full benefits of their investment in basic research (230). Hence, private firms are likely to underinvest in basic research, and Federal support may be necessary.

As R&D projects are more closely targeted to products or processes with commercial potential, however, the argument in favor of Federal support becomes weaker. The private medical device firm is likely to be able to appropriate more fully the benefits of its investment in R&D the closer the project is to a commercializable device. And as research becomes more targeted and specific to a device, the societal gains from full disclosure of research findings decline.

Two conditions suggest that the present level of *private* R&D for medical devices is generally adequate. First, if industrial R&D responds to the demands of the market, as has been suggested by several observers (273,276), then the high level of demand for medical devices resulting from health insurance and other third-party payment for health care would argue that medical devices R&D has been adequately, perhaps more than adequately, stimulated. Second, the $5.4 billion Federal investment in health R&D (404) provides a rich and continuing source of new scientific knowledge that creates opportunities for development of new medical devices.

Against this positive picture for R&D on medical devices is the potentially deleterious effect of premarket regulation on the cost and uncertainty of investment in R&D for new medical devices. A Louis Harris survey reported that because of FDA regulations, 27 percent of responding firms stated that they would not consider developing a new Class III device[10] and another 11 percent stated that they would be unlikely to consider any device development (197).

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[10] A new Class III device must be approved by FDA as safe and effective prior to marketing (see ch. 5).

However, the available evidence seems to suggest that, except perhaps for small firms and manufacturers of Class III devices, the medical devices regulations as they have been implemented have not added substantially to the cost of development, because the vast majority of devices introduced since the passage of medical device regulations in 1976 have not been required to undergo rigorous premarket testing (see ch. 5 for details). However, firms have been subject to some uncertainty about how the regulations would be applied.

The Federal Government has recently embarked on a new strategy—the SBIR program—that does not increase overall R&D budgets but instead shifts the allocation of health R&D funds from other uses to the program's recipients (small firms). The NIH SBIR budget is likely to come at least partially from funds that would otherwise be used for basic research and would go to nonprofit institutions. Therefore, the program probably results in a small net shift of health R&D funds toward the development of medical devices. It is impossible to know whether this shift is in the best interest of society. Given that the SBIR program will consume an increasing proportion of NIH grant and contract funds in the future, continuing scrutiny of the program's grant solicitation and selection methods is advisable.

There are specific areas where increased targeted Federal support of R&D on medical devices may be justified. True orphan devices—those meeting the dual criteria of high per-unit cost of development and distribution relative to potential users' ability to pay and high value in relation to cost—are by definition worthy of support. However, it is difficult to differentiate between devices that lack a sufficient market because those who value them highly cannot afford them and devices that lack a market because their extra benefits to society do not outweigh the costs of bringing them to market. Sound criteria for identifying devices meeting the ideal definition of orphan have not been developed either in the law or in regulations.

The problem of orphan devices may grow as pressures to contain health care costs lead third-party payers to develop increasingly restrictive payment policies. Because the definition of a true orphan device is inextricably linked to the policies of major third-party payers regarding coverage and levels of payment, criteria for identifying orphan devices will have to take these payment policies into account.

There appear to be sound theoretical reasons for supporting development of devices meeting the ideal definitions of orphan: high value in relation to cost and high per-unit cost of development and distribution relative to potential users' ability to pay. Whether in practice there are many devices that meet this definition, however, has not been investigated.

One way to assist the development of orphan devices, apart from providing direct Federal grants and contracts for R&D, would be to amend the Orphan Drug Act (Public Law 97-414) to make orphan devices eligible for the tax credits and grants offered under that act. The act currently provides a 50-percent tax credit for all clinical testing expenses associated with an orphan drug and authorizes the Secretary of Health and Human Services to make grants for clinical testing. It is important to recognize, however, that the currently inadequate definition of orphan products in the law, which depends on the "rare disease" criterion to identify orphan drugs, may encourage devices that are not worth their costs to society to be designated as orphans. Thus, it would probably be premature to change the law until criteria and methods of analysis are developed that will allow for adequate differentiation between devices that lack a market because they are truly orphaned and those that are simply not worth their costs to society.

Option 1: Mandate that DHHS develop criteria and methods for identifying ***true*** *orphan devices.*

This option would be particularly useful now, when Medicare is implementing restrictive new payment policies in hospitals and changes in physician payment are being contemplated. Without adequate methods for assessing the extent to which a given device meets criteria for orphanhood, decisions about R&D subsidies (either through direct grants or tax subsidies) for orphan device development are unlikely to be appropriate.

Because the criteria for orphanhood go well beyond issues of safety, effectiveness, and disease incidence to payment issues, the development of such criteria and methods would probably require participation of a number of constituent agencies of DHHS, including FDA, NIH, and the Health Care Financing Administration.

5.

Regulation of Medical Devices by the Food and Drug Administration

Hearts will never be practical until they can be made unbreakable.

—*The Wizard of Oz*

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5.

Regulation of Medical Devices by the Food and Drug Administration

INTRODUCTION

The Medical Device Amendments of 1976 (Public Law 94-295) consolidated and expanded existing Federal authority over medical devices into a system of regulating the safety and effectiveness of medical devices in proportion to the degree of risk that they pose. In the past 2 years, interest in the law has grown because of problems that have surfaced in implementing some key provisions and because of concerns regarding the costs of some provisions relative to the incremental gains in safety and effectiveness.

The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce held hearings on the Food and Drug Administration's (FDA) implementation of the statute in July 1982 (336) and issued an oversight report in 1983 (338). The General Accounting Office also reviewed implementation of the Medical Device Amendments and issued its report in September 1983 (331). Most recently, in February 1984, the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce held oversight hearings on the law and its implementation (337). These hearings and investigations have focused on FDA's priorities and pace in implementing the amendments and on those provisions of the law which, in view of the experiences gained since the law's enactment, have not worked as intended.

The 1976 law, its history, its implementation by FDA, and key unresolved issues are addressed in this chapter. The chapter concludes with a presentation of a range of options addressed to the major objectives of the law.

LEGISLATIVE HISTORY OF DEVICE REGULATION

Medical device regulation was first authorized in the Federal Food, Drug, and Cosmetic Act of 1938. (This act is best known for requiring premarket notification for the safety of new drugs, a requirement that was extended to include premarket approval of the efficacy as well as the safety of new drugs in the Drug Amendments of 1962.) The 1938 act defined medical devices as (21 U.S.C. § 321 (h)):

> . . . instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, care, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

The 1938 act authorized FDA to inspect any site in which devices were manufactured, processed, packed, or held (21 U.S.C. § 374). It also authorized FDA to seize adulterated or misbranded medical devices; request an injunction against their production, distribution, or use; or seek criminal prosecution of the responsible manufacturer or distributor. But the agency could not take action until *after* a device had been marketed.

In the early regulatory actions taken against adulterated or misbranded devices, FDA was able to use expert testimony to prove its allegations. Over time, however, FDA increasingly had to test devices suspected of violating the law in order to remove these devices from the market (340).

As medical devices became more complex after World War II, attention turned to the regulation of legitimate devices as well. But FDA could still act only *after* devices were distributed and also had the burden of proving that a particular item was misbranded or unsafe, because devices were not subject to *premarket* approval (12). In the late 1960s, however, the courts ruled that certain products (such as nylon sutures and antibiotic-sensitive discs) that fell in the grey area between drugs and devices could legally be considered drugs and subjected to premarket approval requirements for new drugs (12,302); subsequently, FDA regulated as "new drugs" such products as some intrauterine devices (IUDs), some contact lenses, and some in vitro diagnostic products.

Furthermore, during the late 1960s, Congress addressed public health problems associated with radiation emissions from electronic products. Under the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602), Congress established a radiation control program to authorize the establishment of standards for electronic products, including medical and dental radiology equipment.

From the early 1960s to 1975, six Presidential messages were given and 28 bills were introduced to enact medical device legislation.

A 1969 Department of Health, Education, and Welfare review of the scientific literature for injuries associated with medical devices that was conducted by the Cooper Committee (named after its chairman, Theodore Cooper, then Director of the National Heart, Lung, and Blood Institute of the National Institutes of Health) estimated that over a 10-year period, 10,000 injuries were associated with medical devices, of which 731 resulted in death (339).

The vast majority of these problems were associated with three device types: artificial heart valves, 512 deaths and 300 injuries; cardiac pacemakers, 89 deaths and 186 injuries; and intrauterine contraceptive devices, 10 deaths and 8,000 injuries (339). As observers noted, however, there had been no sensational event or public tragedy to spur more stringent regulation of medical devices such as the events leading to the 1962 Drug Amendments (165,328).

Additional examples of hazards associated with medical devices were documented in congressional hearings in 1973. These included prosthetic and orthopedic implants of improper materials, cardiac defibrillators with faulty electrical circuitry, incubators in which temperatures reached as high as 145° F, plastic tracheotomy tubes with obstructions, and faulty valves on emergency oxygen respirators (339).

The developments just described eventually culminated in the enactment of the Medical Device Amendments of 1976 (Public Law 94-295).

THE MEDICAL DEVICE AMENDMENTS OF 1976

The situation prior to enactment of the Medical Device Amendments in 1976 was that FDA could impose premarket approval requirements on only a limited number of devices that could legally be considered new drugs (see above). FDA did have the power to inspect the premises where devices were manufactured and distributed, but had no power to require that owners of these premises notify FDA that they were in the device business. And FDA could attempt to remove mislabeled or unsafe devices only on a case-by-case basis after the devices had been marketed.

As a result of the 1976 Medical Device Amendments, FDA currently has the authority:

- to require that businesses involved with medical devices register their establishments and list their devices annually,
- to impose regulatory requirements (standards or premarket approval) in proportion to the degree of risk of a device, and
- to impose other general controls on all devices to assure safety and effectiveness.

FDA continues to have the authority granted by the 1938 act to inspect any establishment in which devices are manufactured, processed, or packed, whether or not these establishments are exempt from registration.

The definition of medical device was changed in the 1976 amendments to (Public Law 94-295):

> . . . an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is—
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

This last clause in the definition (not achieving its principal purposes through "chemical action within or on the body" and "not dependent upon being metabolized") distinguishes devices from drugs.

Devices are to be categorized by type, on the basis of recommendations from FDA classification panels, into three regulatory classes reflecting their potential risk:

- Class I—general controls,
- Class II—performance standards, and
- Class III—premarket approval.

Class I, general controls, encompasses devices for which general controls authorized by the act are sufficient to provide reasonable assurances of safety and effectiveness. Tongue depressors are an example. Manufacturers of Class I and all other devices must register their establishments and list their devices with FDA, notify FDA at least 90 days before they intend to market the device, and conform to good manufacturing practices. Good manufacturing practices apply to the manufacturing, packing, storage, and installation of devices.

Class II, performance standards, contains devices for which general controls are considered insufficient to ensure safety and effectiveness and information exists to establish performance standards. X-ray devices are an example.

Class III, premarket approval, applies to devices for which general controls are insufficient to ensure safety and efficacy, information does not exist to establish a performance standard, *and* the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury. Cardiac pacemakers are an example.

Preamendments devices were to be so classified and placed in Class I, II, or III. Postamendments devices found to be *"substantially equivalent"* to products on the market before 1976 were to be put into the same class as their preamendments counterparts and could be marketed immediately, although those in Class III could eventually be required to demonstrate safety and effectiveness. Other postamendments devices were to be automatically classified into Class III, although the manufacturer could petition FDA for reclassification into Class I or II; thus, these devices could not be marketed until they had completed FDA premarket approval for safety and effectiveness.

In implementing the 1976 amendments, preamendments Class III devices and their postamendments substantially equivalent counterparts were to be treated differently from truly new postamendments Class III devices. The 1976 amendments stipulate that manufacturers of preamendments Class III devices cannot be required to present safety and effectiveness evidence until 30 months after the effective date of a final classification regulation or until 90 days after publication of a final regulation requiring submission of evidence on safety and effectiveness, whichever period is longer (21 U.S.C. § 351(f)(2)(B)). In the interim, preamendments Class III devices and their postamendments substantial equivalents can continue to be marketed, subject only to the same general controls as applied to Class I devices.

Manufacturers of any of the following devices are required by section 510(k) of the law to notify FDA at least 90 days prior to marketing them:

- a device that is to be marketed for the first time,
- a device or product line that may be similar to one already marketed by another manufacturer, or
- a version of an existing device in a form sig-

nificantly changed or sufficiently modified to affect its safety and effectiveness.

The manufacturer's 510k premarket notification must contain enough information so that FDA can determine whether or not the device is "substantially equivalent" to a device already being marketed. To be found substantially equivalent, a postamendments device need not be identical to a preamendments device, but must not differ markedly in materials, design, or energy source.

The legislative history reflects a congressional intent that the term "substantially equivalent" be construed narrowly where necessary to assure safety and effectiveness, but less narrowly in instances where differences between a postamendments device and a preamendments device did not relate to safety and effectiveness (340). If FDA determines that a postamendments device is substantially equivalent to one already in use, the manufacturer may market the device.

If FDA finds that a device is not substantially equivalent to one already in use before the 1976 amendments, the device must go through a premarket approval process. In this case, it is automatically classified into Class III, although the manufacturer may petition FDA to reclassify it into Class I or Class II. (Class I devices can be marketed, subject only to the general controls summarized earlier. Since FDA has published no performance standards for Class II devices (see section on "Performance Standards" below), these devices have been subject only to general controls.) For a Class III device that is not substantially equivalent to a pre-1976 device, information must be provided to FDA to document its safety and effectiveness before the device can be approved by FDA for marketing.

In order to develop the safety and efficacy information necessary for market approval of a Class III device, the sponsor of such a device may apply to FDA for an "investigational device exemption" (IDE). An IDE, the parallel to the investigational new drug (IND) process in drug regulation, permits limited use of an unapproved device in controlled settings. Upon completion of clinical investigations under the IDE, the sponsor may submit to FDA a premarketing approval application (PMAA) presenting the results of the clinical investigations, an explanation of what the device consists of and how it works, manufacturing data that show compliance with good manufacturing practices, and other information that FDA may require.

If FDA approves this PMAA, the device may be marketed. (The amendments provide an alternative to the IDE/PMAA route to marketing approval for Class III devices, called a "product development protocol," but this has never been used. The major difference between the product development protocol and the IDE/PMAA process is that in the former, FDA would participate in deciding how the device is to be tested. Once the product development protocol is completed, the testing results would be submitted to FDA for approval of the device for marketing (388).)

Finally, the situation for certain "transitional devices" (i.e., devices that were regulated as "new drugs" before enactment of the 1976 amendments) is comparable to that for postamendments devices that are not substantially equivalent to preamendments devices. Transitional devices are automatically classified into Class III, which requires premarket approval, but may be reclassified, subsequent to petitioning FDA, into Class I or Class II.

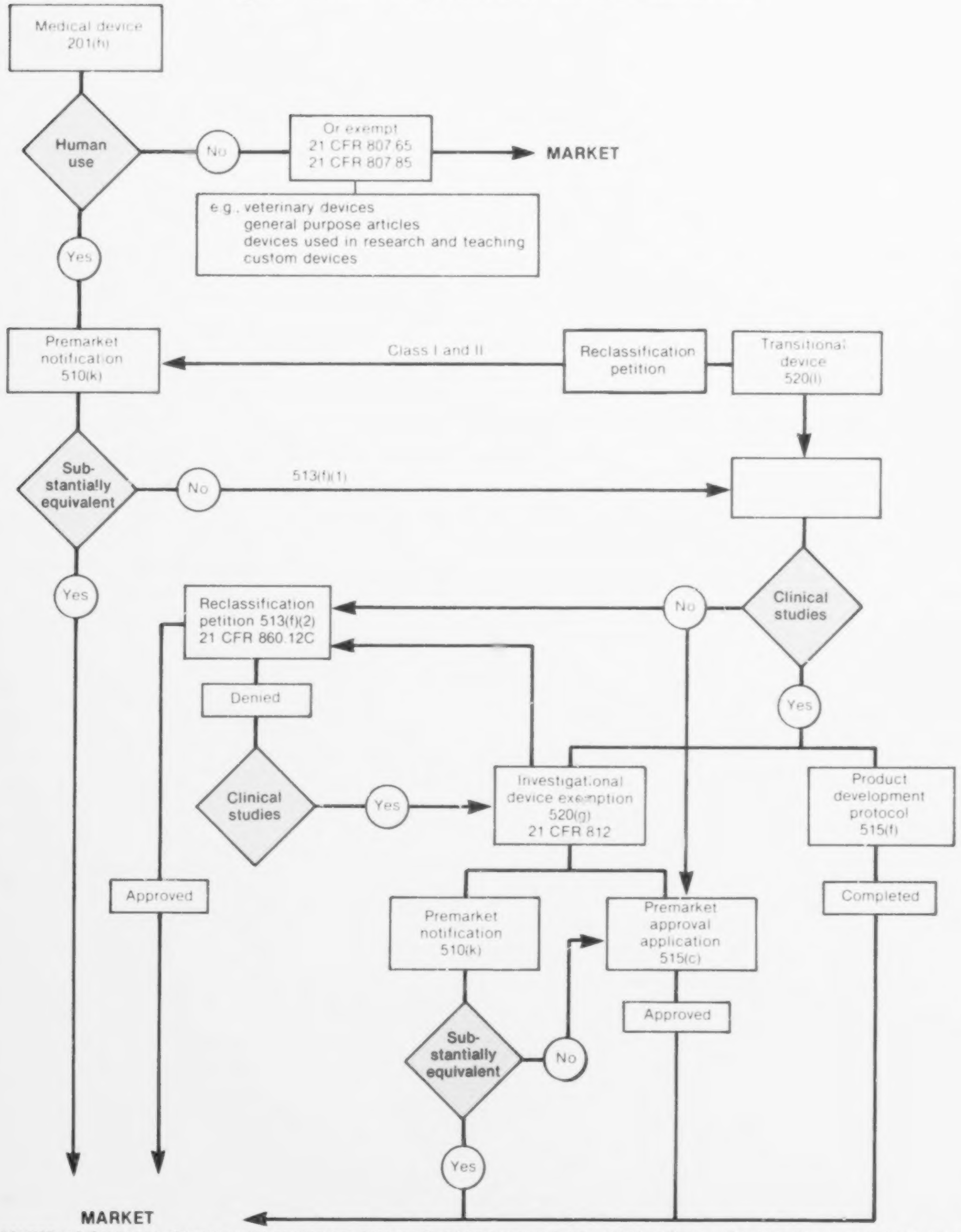
The current process of getting a medical device to market is summarized in figure 1.

The Medical Device Amendments contain other provisions worth noting that are applicable to all medical devices. First, sale, distribution, or use of a device may be restricted by FDA if there cannot otherwise be reasonable assurances of its safety and effectiveness. A device may be banned if it presents substantial deception or an unreasonable and substantial risk of illness or injury.

Second, manufacturers, importers, and distributors of devices may be required to establish and maintain additional records, make reports, and provide information to FDA to assure that their devices are safe and effective.

Third, devices are subject to the color additive provisions of the Federal Food, Drug, and Cosmetic Act, but only if the color additive comes in direct contact with the body for a significant period of time.

Figure 1.—How To Get to Market With a Medical Device


Medical device 201(h)
Human use
No
Or exempt 21 CFR 807.65 21 CFR 807.85
MARKET
e.g., veterinary devices
general purpose articles
devices used in research and teaching
custom devices
Yes
Premarket notification 510(k)
Class I and II
Reclassification petition
Transitional device 520(l)
Sub-stantially equivalent
No
513(f)(1)
Yes
Reclassification petition 513(f)(2) 21 CFR 860.12C
No
Clinical studies
Denied
Yes
Clinical studies
Yes
Investigational device exemption 520(g) 21 CFR 812
Product development protocol 515(f)
Approved
Completed
Premarket notification 510(k)
Premarket approval application 515(c)
Approved
Sub-stantially equivalent
No
Yes
MARKET

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, Bureau of Medical Devices, *Regulatory Requirements for Marketing a Device* (Washington, DC: U.S. Government Printing Office, 1982).

Fourth, because of concern over the impact of the 1976 amendments on small manufacturers, a provision of the law stated that an office should be established to provide technical assistance to small firms. FDA has therefore organized an Office of Small Manufacturers Assistance to help small firms with the regulatory requirements.

Finally, any medical device that can be marketed legally in the United States can be exported legally without further approval by the FDA. Medical devices that have not been approved for use in the United States may also be exported under certain conditions. *Prior FDA approval* is needed for export of devices that: 1) are in violation of performance standards, 2) are subject to premarket approval, 3) are subject to limited use under an IDE, or 4) are banned in the United States. These four types of devices can be exported only if they have the approval of the country to which the device is to be exported, and if FDA has determined that exportation of the device is not contrary to public health and safety (21 U.S.C. § 381(d)(2)). Any other type of device that cannot be marketed in the United States may be exported *without FDA approval* if the device: 1) meets the specifications of the foreign purchaser, 2) does not conflict with the laws of the country of the foreign purchaser, 3) is labeled for export, and 4) is not sold or offered for sale domestically (21 U.S.C. § 381(d)(1)). Although prior FDA approval is not required, FDA can at any time require the exporter of such a device to show that the aforementioned requirements are being met.

IMPLEMENTATION OF THE MEDICAL DEVICE LAW

Registration of Firms and Listing of Devices

Federal regulations require the following businesses involved with medical devices to register their establishments with FDA and list their devices annually (21 CFR pt. 807.20):

- manufacturers and other specified processors of devices,
- manufacturers of device components or accessories that are ready to be used for and labeled for a health-related purpose,
- initiators or developers of device specifications,
- repackagers and relabelers, and
- initial distributors of imported devices.

Manufacturers of device components and raw materials who would not otherwise be required to register, dispensers of devices, licensed medical practitioners, manufacturers of general-purpose articles, manufacturers of devices solely for veterinary use, and manufacturers of devices solely for research and training are exempt from registration (21 CFR pt. 807.65).

The number of device establishments registered with FDA in 1980 was 6,073. (This number differs from the number of establishments cited in ch. 2, mainly because the FDA list includes nonmanufacturing entities such as distributors.) By 1982, the number had increased to 7,636 registered establishments, 6,585 domestic and 1,051 foreign, listing approximately 41,500 products. More than 95 percent of the establishments had fewer than 500 employees, and more than half had fewer than 50 employees (143). Registration lists change significantly from year to year. In 1983, for example, 1,100 firms canceled their medical device status, while 1,800 firms registered for the first time with FDA (206).

Two studies by FDA's Office of Planning and Evaluation measured "baseline" conditions in order to track changes that may occur in the future. Some of the studies' principal findings on device establishments in 1980 were as follows (392):

- Eighty-two percent of registered domestic establishments manufactured devices, 20 percent imported devices, and 22 percent repackaged devices (device establishments may have more than one function).
- Sixty-nine percent of domestic establishments were the sole site operated by the owner/operator, while 28 percent were subsidiaries, branches, or divisions.

- Ninety-three percent of domestic owner/operators (3,948 out of 4,245 in 1980) operated only one medical device establishment.
- Forty-two percent of the domestic establishments had 20 or fewer employees, while 29 percent had 100 or more employees.
- Larger establishments were more likely than small establishments to: 1) produce more types of devices, 2) make an "exclusive" device (a device made by only one or two establishments), 3) make a Class III device, or 4) make a "critical" device (defined below in the section on "Good Manufacturing Practices").
- Sixty-four percent of listed manufacturers made devices in only one medical specialty area (as defined by FDA's list of classification panels).
- Medical device establishments other than those making diagnostic devices averaged 4.4 products each, while diagnostic device establishments averaged 6.4 products each.
- There was little overlap between manufacturers of medical devices and diagnostic devices. Establishments making dental, ophthalmic, and radiological devices were also highly specialized. Therefore, there appears to be a segmentation of the industry between medical and diagnostic devices, and a further segmentation of the medical devices portion of the industry between establishments that are highly specialized and those that make devices in several areas.

The other study (391) looked at "availability" of devices, or the number of products for each device type. A device type may include all products of a particular type (e.g., cardiac pacemakers) or may include groupings of separate types of devices that are similar. The more products of a type, the greater the availability of products of that type. The analysis in this study was based on device classifications that were established enough to use at the time of the analysis, or devices from about half of the FDA classification panels established (see "Classification" section below). Its principal findings on availability were as follows (391):

- On average, there were nine products per type, i.e., each device type was made by an average of nine establishments.
- Product availability was related to class of device. Class I device types averaged 13.1 products per type; Class II, 7.9 products; and Class III, 4.5 products.
- Devices with only one or two manufacturers comprised 28 percent of all device types. Forty-one percent of Class III, 28 percent of Class II, and 24 percent of Class I device types had only one or two manufacturers.
- Foreign establishments made 17 percent of the products examined. Eleven percent of all exclusive types had only foreign manufacturers; 4 percent were made solely by foreign manufacturers.
- Foreign products accounted for 21 percent of Class III devices, 19 percent of Class II, and 15 percent of Class I devices.
- More than one-third of all obstetrics-gynecology products and nearly two-thirds of Class I neurological products were of foreign origin.

Premarket Notification

In addition to listing their devices annually, device establishments must notify FDA through the 510k notification process (see above) when they intend to market new devices.

Postamendments devices that are not found by FDA to be "substantially equivalent" to preamendments devices or to postamendments devices that have been reclassified into Class I or II are presumed to be Class III, and hence to need premarket approval unless the device's sponsor successfully petitions FDA to reclassify the device into Class I or II. However, the overwhelming majority of postamendments devices are from manufacturers who are marketing existing device types for the first time or who have devices that are minor modifications of existing devices. Thus, the 510k premarket notification process, together with the FDA finding that devices are substantially equivalent to preamendments devices, has become the predominant route by which postamendments devices have reached the market.

An indication of the extent to which postamendments devices have been regulated through the 510k notification process is reflected in the fact that, of more than 17,000 notifications received for fiscal year 1977 through fiscal year 1981, only approximately 300 were found to be not substantially equivalent and therefore automatically placed in Class III. For 65 of these, petitions for reclassification were received; 28 were approved, 5 denied, 28 withdrawn or converted to other types of submissions, and 4 were still active at the end of fiscal year 1981. Of the 28 approvals, 3 were reclassified from Class III to I, and 25 from Class III to II (143). The number of 510k submissions and the number of submissions found not substantially equivalent since 1976 are summarized by year in table 32.

The purpose of the 510k notification process was to keep FDA apprised of what was going on in the industry. The concept of "substantial equivalence" was included in the law to address the question of how to treat pre- and postamendments devices fairly. Two issues were involved: 1) a double standard would exist if a postamendments device had to go through the premarketing approval process before it could be marketed, while an identical preamendments device would continue to be marketed; and 2) a type of monopoly would in effect be given to a preamendments device if identical pre- and postamendments devices were treated differently.

The 510k process, together with a determination of substantial equivalence, has been used extensively for postamendments devices to avoid Class III designation and its automatic requirement for premarket approval, or to avoid the involved rulemaking process necessary to reclassify such devices from Class III to Class I or II.

Table 32.—Number of "510k" Submissions and Number Found Not Substantially Equivalent, 1976-83

Year	Number of "510k" submissions	Number found not substantially equivalent
1976 (7 months)	1,362	8
1977	2,427	47
1978	2,180	43
1979	2,714	44
1980	3,316	73
1981	3,652	63
1982	3,780[a]	55
1983	NA[b]	32[d]
Total	19,431[c]	365[d]

[a] Estimate.
[b] NA indicates information not available.
[c] Excluding 1983.
[d] As of July 1983.

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, unpublished data, Silver Spring, MD, 1983.

Use of the substantial equivalence clause to permit the marketing of devices without premarket approval has been encouraged by FDA's regulations and practices. First, FDA's initial proposed regulations that would have required submission of a 510k notice if modifications could affect safety and effectiveness were changed. In the proposed regulations, if FDA determined that modifications could affect safety and effectiveness, there would be no finding of substantial equivalence, and an evaluation of the difference would have been made in a PMAA or in a reclassification petition from automatic Class III designation (53). In the final regulation, however, FDA changed the wording to "changes that could *significantly* affect the safety or effectiveness of the device" (emphasis added) (21 CFR pt. 807.81(a)(3)(i)).

Second, FDA allows manufacturers to trace back through a chain of substantially equivalent postamendments devices to a device on the market before the amendments were enacted. For example, a 1982 device may be approved as substantially equivalent to a 1981 device, which was approved as equivalent to a 1979 device, and so on eventually back to a preamendments device. This practice has been labeled "piggybacking" or, alternatively, "equivalence creep" (53,331).

Third, the amount of data required to show substantial equivalence varies widely, depending on the device. All devices that have been determined *not* to be substantially equivalent and which thus must go through premarket approval are reviewed centrally, but there is no such central review for devices that *have* been found to be substantially equivalent (47).

Another issue relating to the 510k notification process is whether or not notification requirements should be applied to Class I devices. In September 1982, the Scientific Apparatus Makers Association petitioned FDA to drop 510k notification requirements for Class I device types and to simplify reporting requirements for Class II and III (82). The petition claimed that Class I devices would still be subject to the registration requirements and to surveillance under the good manufacturing practices regulations.

Furthermore, notification of intent to market Class II devices for which no standards exist could be simplified, and additional information could be required only for Class III devices and for Class II devices that have performance standards. The petition claimed that these changes would still provide reasonable assurances against new devices being marketed without a change in classification or without premarket approval.

FDA subsequently denied the petition, telling the Scientific Apparatus Makers Association that the legislative intent was to make decisions on the basis of generic types of devices, not whether or not devices were in Class I (80). In addition, FDA was already exempting some device types from 510k notification requirements. For example, in its final rule on classifying General Hospital and Personal Use devices, FDA exempted 30 generic types of Class I devices from notification requirements. They included medical absorbent fibers and specimen containers, if the devices are not labeled or otherwise represented as sterile (306).

Classification of Devices

By the beginning of 1984, FDA had completed classification of preamendments device types in only 11 of its 19 medical specialty sections and had issued proposed classifications for the other 8 sections (see table 33). Final and proposed classifications as of February had placed 460 device types in Class I, 1,086 in Class II, 138 in Class III, and, depending on the particular product or use of the product of a specified device type, 27 in Class I or II, 13 in Class II or III, and one in Class I, II, or III (see table 34).

A "device type" may include all products of a particular type (see discussion of availability in the section above, "Registration of Firms and Listing of Devices") or may include groupings of separate types of devices that are similar. Thus, for example, the device type "obstetrics-gynecology specialized manual instruments" was formed by merging 18 separate instruments such as umbilical clamps, gynecological surgical forceps, and uterine sounds (391).

Documentation of safety and effectiveness for preamendments Class III devices was not immediately required but eventually has to be submitted for marketing to continue. As previously explained, the 1976 amendments provided a grace period of 30 months before such requirements could be imposed, but the grace period does not begin until final classification is made. Therefore, for example, the earliest date that FDA could call for evidence of safety and effectiveness of Class III devices in the eight medical specialty sections for which final classifications had not been made at the beginning of 1984, even if they were finally classified early in the year, would be in 1986. For the 11 medical specialties with final classifications, the grace period had ended for 6 by 1984 (see table 34).

Tables 33 and 34 show the number of Class III device *types* for which the 30-month grace period applies. An indication of the number of device *products* that are involved can be gleaned from the number of postamendments Class III devices found to be substantially equivalent to preamendments Class III devices. The number of such products is summarized in table 35 by medical specialty and year of notification. From the table, it can be seen that, in addition to Class III products on the market prior to the 1976 amendments, there were over 1,000 postamendments Class III products in use by 1983 through a finding of substantial equivalence. Nearly two-thirds of these products were cardiovascular devices.

On May 5, 1982, the Health Research Group petitioned FDA to issue regulations requiring device manufacturers to submit PMAAs for preamendments Class III neurological devices (252). These devices had been classified in final regulations effective October 4, 1979, and the Health Research Group had petitioned FDA shortly after the 30-month grace period had ended. FDA's response was that the 30-month time period established only the *earliest* date FDA could act (85).

The Health Research Group subsequently wrote to Rep. John Dingell (D-Mich.), Chair of the House Committee on Energy and Commerce and also Chair of its Subcommittee on Oversight and Investigations, asking that oversight hearings be held and that there be consideration of an amend-

Table 33.—Classification of Preamendments Device Types by Medical Specialty Category, February 1984

			Class						
Medical specialty category	Proposed	Final	I	II	III	I or II	II or III	I, II, or III	Total
Neurology	11/28/78	9/4/79	24	66	11	0	0	0	101
Cardiovascular	4/9/79	2/5/80	3	108	24	1	2	0	138
Obstetrics-gynecology	4/3/79	2/26/80	5	48	16	0	0	0	69
Hematology	9/11/79	9/12/80							
(combined)			42	60	6	0	1	0	109
Pathology	9/11/79	9/12/80							
General hospital and personal use	8/24/79	10/21/80	51	39	2	2	0	0	94
Anesthesiology	11/2/79	7/16/82	21	105	7	0	1	0	134
Immunology	4/22/80	11/9/82							
(combined)			93	64	5	0	0	0	162
Microbiology	4/22/80	11/9/82							
Physical medicine	8/28/79	11/23/83	32	42	2	0	5	0	81
Gastroenterology-urology	1/23/81	11/23/83	9	32	9	4	2	0	56
Subtotal			280	564	82	7	11	0	944
Dental	12/30/80	—	49	122	13	1	0	0	185
General and plastic surgery	1/19/82	—	23	25	5	0	1	0	54
Ear, nose, and throat	1/22/82	—	10	47	10	0	0	0	67
Ophthalmology	1/26/82	—	45	51	4	19	0	0	119
Radiology	1/29/82	—	7	64	0	0	1	1	73
Clinical chemistry	2/12/82	—							
(combined)			31	175	0	0	0	0	206
Clinical toxicology	2/12/82	—							
Orthopedics	7/2/82	—	15	38	24	0	0	0	77
Subtotal			180	522	56	20	2	1	781
Total			460	1,086	138	27	13	1	1,725

SOURCE: *Federal Register* publications of specified dates.

Table 34.—Classification Status of Preamendments Device Types, February 1984

	Class						
Status	I	II	III	I or II	II or III	I, II, or III	Total
Final	280	564	82	7	11	0	944
Proposed	180	522	56	20	2	1	781
Total	460	1,086	138	27	13	1	1,725

SOURCE: See table 33.

ment to the device amendments that would clearly establish a definite time for submission of data for preamendments and substantially equivalent Class III devices (83). The Health Research Group petitioned FDA again in March 1983, this time for preamendments Class III obstetrics-gynecology devices and their substantial equivalents, pointing out that the 30-month grace period had ended on August 31, 1982 (253).

In September 1983, FDA issued its first "Notice of Intent" to initiate proceedings requiring approval for continued marketing of preamendments Class III devices and their postamendments substantial equivalents in the five medical specialty categories for which the 30-month grace period had expired. FDA identified the following devices in these five medical specialty categories as being the first device types for which safety and effectiveness evidence would be required (321).

- Hematology and Pathology (combined)
  1. Automated differential cell counter
  2. Automated heparin analyzer
  3. Automated blood cell separator
- Cardiovascular
  1. Implantable pacemaker pulse
  2. Pacemaker programmer
  3. Replacement heart valve
- General hospital and personal use
  1. Infant radiant warmer
- Neurology
  1. Implanted cerebellar stimulator
  2. Implanted diaphragmatic/phrenic nerve stimulator
  3. Implanted intracerebral/subcortical stimulator for pain relief

Table 35.—Number of Postamendments Class III Devices Found Substantially Equivalent to Preamendments Devices by Medical Specialty Category, 1976-83

Medical specialty category	1976 (7 mos.)	1977	1978	1979	1980	1981	1982	1983 (as of 7/83)	Total
Anesthesiology[a]	1	3	5	3	9	3	1	2	27
Cardiovascular[a]	33	71	89	121	114	143	94	51	716
Clinical chemistry	0	0	0	0	1	2	0	0	3
Clinical toxicology	0	0	0	0	0	1	0	0	1
Dental	2	6	5	5	4	6	11	3	42
Ear, nose, and throat	0	3	3	6	5	0	3	0	20
Gastroenterology-urology[a]	0	4	2	3	8	5	8	10	40
General and plastic surgery	6	5	2	6	5	14	2	5	45
General hospital and personal use[a]	0	1	0	2	2	2	2	1	10
Hematology[a]	0	9	2	8	4	0	3	1	27
Immunology[a]	1	4	1	1	3	3	2	1	16
Microbiology[a]	0	5	4	8	12	10	3	1	43
Neurology[a]	5	6	2	3	8	5	2	0	31
Pathology[a]	0	0	0	0	0	0	2	0	2
Obstetrics-gynecology[a]	2	2	3	1	3	2	0	2	15
Ophthalmology	2	3	7	5	3	3	9	6	38
Orthopedics	0	1	0	1	2	2	0	2	8
Physical medicine[a]	0	1	1	1	0	0	0	0	3
Radiology	0	0	0	1	0	1	3	0	5
Total	52	124	126	175	183	202	145	85	1,092

[a] Classification completed (as of the end of 1983) (see table 33).

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, unpublished data, Silver Spring, MD, 1983.

- Obstetrics-gynecology
  1. Transabdominal amnioscope (fetoscope) and accessories
  2. Contraceptive uterine device (IUD) and introducer
  3. Contraceptive tubal occlusion device (TOD) and introducer

The *Federal Register* notice also announced that FDA was proposing a rule to require the filing of a PMAA for one of these devices, the implanted cerebellar stimulator. Four months after the announcement, no PMAAs had been submitted, probably because of difficulty in providing data that supported the stimulator's safety and effectiveness (86). If IDEs are obtained, however, the implanted cerebellar stimulator may continue to be used for the limited purpose of obtaining safety and effectiveness data from clinical trials (321).

Reclassification of Devices

As explained earlier, the sponsors of postamendments devices that are not substantially equivalent to preamendments devices and are automatically put in Class III may petition FDA for reclassification into Class I or II. The major reclassification issue has not been with these devices, however, but with one of the transitional devices—contact lenses.

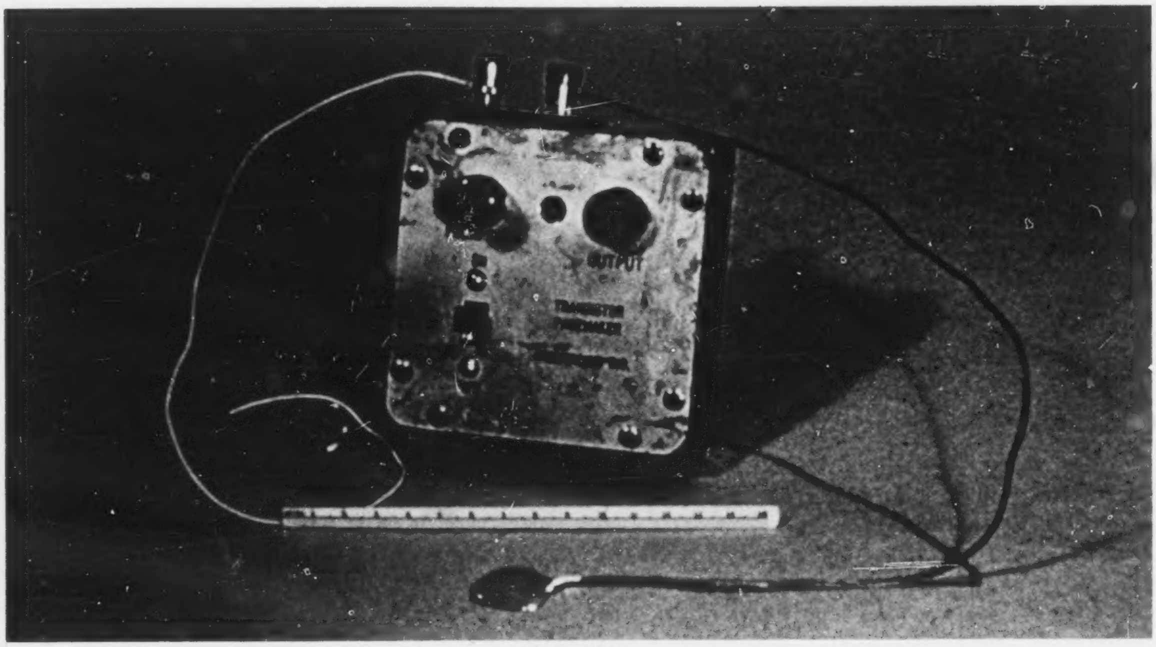
Under the 1976 Medical Device Amendments, transitional devices (products that had previously been regulated as "new drugs") were automatically classified in Class III and made subject to premarket approval requirements, although the manufacturers could petition FDA for reclassification. All contact lenses made of polymers other than polymethyl-methacrylate (hard lenses) had been previously declared to be "new drugs" and placed in Class III when the 1976 amendments were enacted. Subsequently, some manufacturers did the testing required to meet the premarket approval requirements.

In March 1981, the Contact Lens Manufacturers Association (CLMA), representing predominantly small contact lens manufacturers, petitioned FDA to reclassify from Class III to II contact lenses consisting principally of rigid plastic materials. CLMA's contention was that these lenses were safe and effective enough to be placed in Class II, thus making further testing unnecessary.

FDA subsequently concluded that CLMA's petition did not meet all of the requirements of the regulations (21 CFR pt. 860.123). The agency also

1932

Early 1950s



Mid 1970s

Photo credits: Alan R. Kahn

This picture shows three steps in the evolution of the cardiac pacemaker, from a device carried on the patient's back, to an external device with internal leads, to a fully implantable pacemaker. Implantable cardiac pacemakers are regulated as Class III devices.

determined that the objective of CLMA's petition was meritorious, however, and in November 1982, proposed to reclassify both daily-wear soft contact lenses and daily-wear rigid gas-permeable contact lenses from Class III to Class I (rather than to Class II) (313).

In December 1983, FDA withdrew the proposed rule on rigid gas-permeable lenses on the basis of the fact that its review found insufficient publicly available, valid scientific evidence to show that the device was safe and effective (323). The information had to be based on "valid scientific evidence" (21 CFR pt. 860.7(c)), and that evidence had to be publicly available because the 1976 amendments prohibit the use of trade secrets, confidential commercial information, or detailed information on safety and effectiveness contained in the premarket approval application of manufacturers who have succeeded in obtaining approval for their devices.

Following its decision not to down-classify rigid gas-permeable contact lenses, however, FDA decided to review its contact lens guidelines for IDEs and PMAAs to determine under what conditions some parts of the guidelines could be avoided, thereby simplifying the premarket approval process (207).

Good Manufacturing Practices

Good manufacturing practices regulations, which apply to the manufacturing, packing, storage, and installation of devices, are one of the important ways in which Class I devices were to be regulated. They also apply to Class II and III devices.

The good manufacturing practices regulations implemented by FDA for device manufacturers distinguish between "critical" and "noncritical" devices (21 CFR pt. 820):

> "Critical device" means a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user.
>
> "Noncritical device" means any finished device other than a critical device.

Most critical devices are in Class III, but not all Class III devices are critical.

The good manufacturing practices regulations require that the manufacturer keep a device master record containing the device's specifications, production processes, and quality assurance procedures; a historical record of the device indicating control numbers and dates of manufacture and distribution; and complaint files regarding the device's performance. For critical devices, the manufacturer must have more detailed monitoring of production and distribution and must maintain individual control numbers and device master records. Additional compliance programs are cited specifically for manufacturers of cardiac pacemakers and sterile devices (389). FDA has exempted manufacturers of some noncritical devices in Class I (e.g., specimen containers) from most of the recordkeeping requirements of the good manufacturing practices regulations.

In a review of reports of good manufacturing practice inspections conducted primarily on Class II and III device manufacturers from January 1979 through December 1981, out of 3,811 good manufacturing practices inspections, 62 regulatory actions were taken. FDA concluded that the compliance rate for larger firms tended to be somewhat better than for smaller firms, but overall compliance by the industry was good, and there was a reasonable level of compliance for smaller firms (143).

Performance Standards

Proposed and final classifications as of early 1984 had placed nearly 1,100 of the more than 1,700 device types in Class II (see tables 33 and 34, above). Yet no mandatory performance standards have been issued by FDA for any Class II device types.

Class II has become a de facto catchall regulatory category, intermediate between the minimum regulatory requirements imposed by Class I general controls and the full premarket approval process associated with Class III devices. Operationally, however, because no performance standards have been issued for Class II device types, Class II devices have been regulated as though they were Class I devices.

FDA has approached further regulation of Class II device types in several ways. First, in 1982, FDA proposed that the following steps could be considered before promulgation of a mandatory performance standard (387):

- request that manufacturers voluntarily solve device problems,
- publicize particular device problems,
- publish educational and technical information directed at device use,
- participate in developing a voluntary standard,

- make use of other general controls such as those for adulteration and misbranding, and
- develop guidelines.

Second, in mid-1982, the Administration submitted to Congress a proposal to repeal the present statutory procedures for developing and establishing performance standards for medical devices by substituting a simpler notice-and-comment rulemaking procedure under the Administrative Procedures Act. The device amendments require a five-step process: 1) initiate by *Federal Register* notice a proceeding for a performance standard, which provides the opportunity for manufacturers to request a change in classification, denial of requests for reclassification, or initiation of reclassification by *Federal Register* notice; 2) invite persons by *Federal Register* notice to submit an existing standard as a proposed performance standard or an offer to develop such a standard; 3) accept or reject such offers or proceed to develop such standards; 4) publish a notice of proposed rulemaking; and 5) promulgate a performance standard (21 CFR pt. 861.20).

The proposal the Administration submitted to Congress would have eliminated the second and third steps. Rep. Henry A. Waxman (D-Calif.), Chair of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, agreed to sponsor the bill but added a section requiring manufacturers to notify FDA if they learn of device defects that present unreasonable risks of substantial harm (see subsequent section on "Postmarketing Surveillance" for a related discussion). H.R. 7052, the Medical Device Amendments of 1982, was introduced by Rep. Waxman on August 19, 1982, but was not acted on. Similar legislation, including discretionary authority to apply performance standards, was reported to be under consideration at the Department of Health and Human Services/FDA at the beginning of 1984 (87).

Third, in mid-1983, FDA finally identified 11 priority Class II devices, announced its intent to proceed with development of performance standards, and started the five-step process (see above) by providing the opportunity to submit a request for a change in the classification of the first of these 11 devices, the continuous ventilator (320).

Do the 1976 Medical Device Amendments in fact *require* the use of performance standards? Two sections of the amendments seem in conflict on this point. Section 514(a)(1) of the act states that: "The Secretary *may* by regulation . . . establish a performance standard for a Class II device" (emphasis added). But the act's definition of a Class II device is: "A device which cannot be classified as a Class I device because the [Class I] controls . . . by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, *for which there is sufficient information to establish a performance standard* to provide such assurance, and for which *it is therefore necessary to establish for the device a performance standard* . . . to provide reasonable assurance of its safety and effectiveness" (emphasis added) (§ 513(a)(1)(B)).

What if there is *insufficient* information to establish a performance standard? That condition in itself does not require Class III designation. A device is a Class III device if it "cannot be classified as a Class II device because insufficient information exists for the establishment of a performance standard . . . *and* (it) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury" (emphasis added) (§ 513(a)(1)(C)). FDA, in classifying a device into Class II, has had to conclude that sufficient information to develop performance standards in fact exists (see the definition of Class II, above). Yet the fact that no mandatory performance standards have been issued casts doubt on this conclusion.

Moreover, FDA has chosen Class II instead of Class III designation even in some cases where a device was of an implantable type. This is illustrated by proposed classifications for General and Plastic Surgery devices, where seven implantable device types (including artificial chins, ears, and noses) were proposed for Class II instead of Class III designation (311). The Health Research Group, commenting on these proposed classifications, stated that implantable devices should be in Class III (253).

Investigational Device Exemptions

An IDE permits limited use of an unapproved Class III medical device in controlled settings for the purpose of collecting data on safety and effectiveness. This information can subsequently be used in support of a PMAA.

The regulations that FDA has implemented on IDEs make a distinction, which is not expressly stated in the law, between "significant risk" and "nonsignificant risk" devices. A "significant risk device" is an investigational device that (21 CFR pt. 812.3(m)):

(1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
(2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
(3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
(4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Sponsors of investigations of significant risk devices must obtain approval by an institutional review board, if one exists, and must also apply for an IDE from FDA. Investigations may not begin until FDA approval is granted. The determination of whether a device is a significant risk device is initially made by the sponsor. The institutional review board reviewing the investigational plan also makes this determination and has the authority to approve, require modifications, or disapprove the investigational plan. If the review board disagrees with a sponsor's conclusion that a device is a nonsignificant risk device, the sponsor has to notify FDA and apply for an IDE.

If no institutional review board exists or if FDA finds the institutional review board's review inadequate, the sponsor may submit an application for an IDE directly to FDA (21 CFR pt. 812.62). FDA will then decide whether an IDE is needed. The sponsor of a nonsignificant risk device need not apply for an IDE but must obtain approval to test the device from the institutional review board of the institution where testing will occur and must meet certain reporting, recordkeeping, and monitoring requirements.

The IDE not only allows device sponsors to test the Class III device before approval is obtained for marketing, but also is a method of keeping FDA apprised of the existence of clinical testing. For nonsignificant risk devices, FDA need not actually be informed of the specifics of testing, and these devices are considered to have approved applications for IDEs as long as the institutional review board has approved the testing and certain recordkeeping and other requirements are met (21 CFR pt. 812.2(b)).

(At a December 1983 meeting of the Food and Drug Law Institute, an FDA official unofficially raised the idea of a written notification to FDA of the existence of a nonsignificant risk investigation in addition to the normal nonsignificant risk IDE procedures. The principal purpose was to inform FDA of the existence of clinical testing to ensure that a reasonable amount of safety and effectiveness information was gathered in preparation for premarket approval, and to prevent manufacturers from profiting on unapproved devices (81).)

In a few instances, FDA guidelines have established requirements concerning the numbers of patients required in a clinical study and the length of time they need to be followed. For example, in December 1983 FDA advised manufacturers of YAG (yttrium aluminum garnet) lasers, a Class III device which is used in cataract surgery, that a reasonable study population was 500 patients studied for 6 months and that the sponsors should not add to the study without FDA approval (81).

The number of significant risk IDEs that have been issued from 1977 to 1982 is summarized in table 36 by medical specialty category. The numbers in that table reflect the changing status of the IDE regulations. Until 1978, FDA required IDE applications solely for studies of certain Class III devices that had been previously regulated as new drugs (i.e., "transitional devices"). In February 1978, the IDE regulations for intraocular lenses became effective (21 CFR pt. 813), and IDE ap-

Table 36.—Investigational Device Exemptions (IDEs) for Significant Risk Devices by Medical Specialty Category, 1977-82

Medical specialty category	1977	1978[a]	1979	1980[b]	1981	1982	Total
Anesthesiology	0	0	0	0	8	11	19
Cardiovascular	0	3	2	21	39	32	97
Clinical chemistry	0	0	2	0	0	1	3
Clinical toxicology	0	0	0	0	0	0	0
Dental	0	0	1	4	0	2	7
Ear, nose, and throat	0	0	0	1	1	4	6
Gastroenterology-urology	0	0	1	10	28	21	60
General and plastic surgery	4	1	2	5	7	12	31
General hospital and personal use	2	0	0	4	4	4	14
Hematology	0	0	0	0	0	0	0
Immunology	0	1	0	2	2	0	5
Microbiology	0	0	0	1	0	0	1
Neurology	0	0	3	2	4	9	18
Pathology	0	0	0	0	0	0	0
Obstetrics-gynecology	0	0	0	21	53	34	108[c]
Ophthalmology	1	48	21	24	34	34	162
Orthopedics	0	0	0	4	12	11	27
Physical medicine	0	0	1	0	2	0	3
Radiology	0	0	0	6	9	1	16
Total	7	53	33	105	203	176	577

[a] Intraocular lens regulation final in February 1978.

[b] IDE regulation final in January 1980.

[c] Almost exclusively cervical cap studies.

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, unpublished data, Silver Spring, MD, 1983.

plications for intraocular lenses began to be received. In January 1980, IDE regulations applicable to other types of devices were made final (21 CFR pt. 812).

The relationship between requests for approval and FDA's finding that IDEs were in fact needed is indicated by the fact that nearly 60 percent of approximately 400 requests for approval of IDEs for significant risk devices that FDA received between July 1981 and July 1982 were approved with or without additional conditions within 30 days. The remainder were disapproved, subject to additional justification, withdrawn by the sponsor, or returned to the sponsor with the finding that an IDE was not necessary (143).

Premarket Approval

In 1980, FDA developed guidelines for the submission of PMAAs and also published proposed regulations on premarket approval requirements (308). However, the regulations had not been finalized by early 1984. Under the guidelines currently in use, when a PMAA is approved, the approval letter states that information on adverse reactions and device defects must be reported within 10 days. And according to an FDA prescription device regulation (21 CFR pt. 801.109) predating the 1976 amendments, certain devices may be sold or distributed only by or on the order of licensed practitioners. FDA has used these restrictions as a condition of approval for certain devices.

As indicated earlier, the only types of devices that have had to go through the full premarket approval process so far are: 1) postamendments devices that are not substantially equivalent to preamendments devices, and 2) "transitional devices" that have not been reclassified as Class I or II and postamendments devices substantially equivalent to them. Preamendments Class III devices and their postamendments equivalents will eventually have to go through a similar approval process. In September 1983, FDA identified the first 13 preamendments Class III device types for which evidence of safety and effectiveness will soon be required if continued marketing is to be allowed (see section on "Classification of Devices," above) (321).

The number of postamendments Class III devices that have successfully passed through the full premarket approval process and the number of transitional devices that have received premarket approval from 1977 to 1982 are summarized in table 37 by medical specialty category.

Table 37.—Approved Premarket Approval Applications (PMAAs) by Medical Specialty Category, 1977-82

Medical specialty category	1977	1978	1979	1980	1981	1982	Total
Approved PMAAs:							
Anesthesiology	0	0	0	1	3	4	8
Cardiovascular	1	0	4	2	3	5	15
Clinical chemistry	0	0	0	0	1	0	1
Clinical toxicology	0	0	0	0	0	0	0
Dental	0	0	1	0	1	0	2
Ear, nose, and throat	0	0	0	0	0	0	0
Gastroenterology-urology	0	0	1	0	0	2	3
General and plastic surgery	0	0	0	4	4	2	10
General hospital and personal use	0	0	0	1	2	2	5
Hematology	0	0	0	0	0	0	0
Immunology	0	0	0	3	0	0	3
Microbiology	0	0	5	4	2	1	12
Neurology	0	0	0	0	1	2	3
Pathology	0	0	0	0	0	0	0
Obstetrics-gynecology	0	0	0	0	0	0	0
Ophthalmology	0	0	6	12	22	20	60
Orthopedics	0	0	2	1	1	2	6
Physical medicine	0	0	0	0	0	0	0
Radiology	0	0	0	0	0	0	0
Total	1	0	19	28	40	40	128
Approved PMAAs for new devices:							
Anesthesiology	0	0	0	1	3	4	8
Cardiovascular	1	0	3	2	2	5	13
Clinical chemistry	0	0	0	0	1	0	1
Clinical toxicology	0	0	0	0	0	0	0
Dental	0	0	1	0	0	0	1
Ear, nose, and throat	0	0	0	0	0	0	0
Gastroenterology-urology	0	0	1	0	0	2	3
General and plastic surgery	0	0	0	0	2	1	3
General hospital and personal use	0	0	0	1	2	2	5
Hematology	0	0	0	0	0	0	0
Immunology	0	0	0	0	0	0	0
Microbiology	0	0	5	4	2	1	12
Neurology	0	0	0	0	1	2	3
Pathology	0	0	0	0	0	0	0
Obstetrics-gynecology	0	0	0	0	0	0	0
Ophthalmology	0	0	0	0	0	0	0
Orthopedics	0	0	2	1	0	1	4
Physical medicine	0	0	0	0	0	0	0
Radiology	0	0	0	0	0	0	0
Total	1	0	12	9	13	18	53
Approved PMAAs for transitional devices:							
Anesthesiology	0	0	0	0	0	0	0
Cardiovascular	0	0	1	0	1	0	2
Clinical chemistry	0	0	0	0	0	0	0
Clinical toxicology	0	0	0	0	0	0	0
Dental	0	0	0	0	1	0	1
Ear, nose, and throat	0	0	0	0	0	0	0
Gastroenterology-urology	0	0	0	0	0	0	0
General and plastic surgery	0	0	0	4	2	1	7
General hospital and personal use	0	0	0	0	0	0	0
Hematology	0	0	0	0	0	0	0
Immunology	0	0	0	3	0	0	3
Microbiology	0	0	0	0	0	0	0
Neurology	0	0	0	0	0	0	0
Pathology	0	0	0	0	0	0	0
Obstetrics-gynecology	0	0	0	0	0	0	0

Table 37.—continued

Medical specialty category	1977	1978	1979	1980	1981	1982	Total
Ophthalmology	0	0	6	12	22	20	60
Orthopedics	0	0	0	0	1	1	2
Physical medicine	0	0	0	0	0	0	0
Radiology	0	0	0	0	0	0	0
Total	0	0	7	19	27	22	75

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, unpublished data, Silver Spring, MD, 1983.

Approved transitional devices are heavily skewed toward ophthalmic products, which are almost exclusively contact lenses and contact lens cleaning solutions and, beginning in December 1981, intraocular lenses. Other examples of transitional devices include cardiovascular grafts, bone cement, absorbable sutures, and specific types of immunological tests.

"New" postamendments devices are also concentrated in a few medical specialties, but not to the extent that ophthalmic devices have dominated approved transitional devices. Among these new devices are cardiac valves, heart pacemakers and accessories, cardiovascular catheters, life-support monitoring systems, implantable infusion pumps, artificial hips, and antibody tests for infectious agents.

From 1977 through the end of 1982, 128 Class III products (53 "new" devices and 75 "transitional" devices) had gained premarket approval. During the same period, 1,007 Class III products were approved for marketing through the finding that they were substantially equivalent to preamendments Class III device types (compare tables 35 and 36). As previously noted, evidence of safety and effectiveness has not yet been required for these postamendments Class III products found substantially equivalent to preamendments devices. Many of these applications for postamendments Class III devices are for modifications of devices which were already commercially available.

Postmarketing Surveillance

There are a number of existing and potential methods to monitor hazards associated with the use of devices that have been marketed. FDA maintains a Device Experience Network (DEN) that receives voluntary reports on device hazards; can require repair, refund, or replacement of devices for hazards or defects; and requires that manufacturers keep records of complaints as part of the good manufacturing practices regulations. Two other methods have been mentioned earlier. A condition of approval for new Class III devices approved through the full premarket approval process is that information that manufacturers receive on device defects and adverse reactions has to be reported to FDA within 10 days. And manufacturers, importers, and distributors of devices may be required to provide FDA with information to ensure that their devices are safe and effective.

The major issue in postmarketing surveillance activities has involved the authority that the 1976 amendments gave to FDA to require that information be provided to FDA to ensure that devices already on the market are safe and effective. In late 1980, FDA proposed rules for mandatory device experience reporting, under which manufacturers and distributors of medical devices would be required to submit reports on devices that: 1) may have caused a death or injury, 2) may have a deficiency that could cause a death or injury or that could give inaccurate diagnostic information that could result in improper treatment, or 3) are the subject of a remedial action by the manufacturer (307). Any death that might have been caused by a device would have had to be reported within 72 hours of the manufacturer's or distributor's receipt of that information, with a followup report submitted within 7 working days. Reports also would have had to be submitted within 7 working days after receiving information of any actual or possible device deficiency that could result in a death or injury.

FDA's rationale for a mandatory device reporting regulation was twofold. Practitioners and users of medical devices usually do not report device experiences to FDA but instead contact the manufacturer for information and advice. Reports would be required even if the manufacturer determined that the death or injury was not due to the device or that there was no deficiency, because FDA expected that few devices would be characterized by their manufacturers as having deficiencies, few reports would be submitted, and reporting of confirmed deficiencies would be delayed if manufacturers first investigated before reporting (307).

A year later, in late 1981, the proposed rule was held in abeyance because of comments that the requirements were overly broad and because of issuance in early 1981 of Executive Order 12291 on "Federal Regulation," under which regulatory actions are to be taken only when the potential benefits of the action outweigh the potential costs. FDA also announced that it would inspect complaint files maintained under the good manufacturing practices regulations to determine if they could be used as an adequate or partial substitute for the proposed rule (309). A pretest, phase I of the review of good manufacturing practices complaint files was completed on December 31, 1981, and phase II started on July 14, 1982, involving a review of the complaint files of 418 firms.

In May 1983, FDA issued a reproposal on medical device reporting, under which reports would be required within 15 days of receiving information that "reasonably suggests, or a person alleges and the manufacturer or importer is aware of the allegation" that one of its marketed devices "has caused or contributed to" a death or serious injury or "has malfunctioned" and, if the malfunction occurs, "is likely to" cause or contribute to a death or serious injury (318).

Data analysis of the phase II review of good manufacturing practices complaint files had been completed by early 1984, and the report was expected to be available sometime in 1984. FDA has concluded that the good manufacturing practices complaint files would not be an adequate substitute for a mandatory device reporting regulation for several reasons. First, inspection of complaint files would not lead to timely reporting. Good manufacturing practices inspections are conducted every 2 years, and FDA did not expect more frequent inspections in the future. Second, with over 6,000 establishments to inspect, there would be a problem with deciding which and how many establishments to inspect. Third, the way in which good manufacturing practices records are kept would lead to practical difficulties in collecting the information for adverse experience information. As a consequence, FDA expects to reissue a revised mandatory device reporting proposal in 1984, subject to clearance by the Office of Management and Budget and other Federal agencies (257).

FDA, in its proposals for a mandatory device reporting regulation, has stated that its voluntary reporting system—the Device Experience Network, or DEN—is not an adequate substitute. DEN is not a comprehensive reporting program, and FDA does not have the resources to maintain constant contact with all device users to encourage reporting. Furthermore, device manufacturers are the most knowledgeable about their products and their associated risks and are in the best position to report to FDA. But few manufacturers report under the DEN system, and many of the reports that they make are trade complaints about a competitor's product, not reports from the manufacturers of the devices in question. And in some cases, device manufacturers report device problems to FDA only after a product recall or other remedial action is completed (318).

Reviews of DEN data on Class III devices and of recalls prompted by a hazard with a high likelihood of serious injury or death resulted in the following observations (based on information provided OTA by FDA for the period from 1976 to mid-1983). From the DEN system: deaths allegedly associated with devices were reported most frequently for pacemakers and heart valves; actual injury, reported most frequently with pacemakers, heart valves, IUDs, and to a lesser degree but still relatively frequently, with intraocular lenses; and potential injury, reported most frequently with resuscitation equipment (usually associated with power failure or other electrical malfunction), intra-aortic balloon pumps or catheters, pacemakers, heart valves, and intraocular lenses.

Recalls prompted by risks of serious injury or death were most frequent for cardiovascular devices, with pacemakers again comprising the largest subgroup. Thus, the DEN system and recalls for high risks mostly involve implantable devices, often involve electrical problems, and often involve cardiovascular devices.

The DEN system of voluntary reporting and product recall information do not provide adequate information on the magnitude and frequency of device-related problems. Voluntary reporting also includes allegations of death or injury that may not be associated with the device in question or may be user-related and not due to device defects. FDA also cautions against using DEN for trend analysis, because reports are voluntary, use of the system has changed over time, and the number of reports therefore may reflect trends in DEN participation and other factors (48). However, voluntary reporting does provide indications of the types of devices that have associated risks, and product recall information identifies devices with significant actual or potential risks.

Other Provisions of the Law

Restricted Devices

Section 520(e) of the Medical Device Amendments added a provision for "restricted devices" authorizing FDA to issue regulations imposing restrictions on the sale, distribution, or use of devices. FDA was also authorized to regulate advertising of restricted devices and to inspect manufacturers' records related to restricted devices. Prior to the amendments, the sale and distribution of some devices were authorized only through "prescriptions" by designated persons (e.g., physicians) (21 CFR pt. 801.109). Immediately following the enactment of the law, FDA published a notice announcing that FDA considered "restricted devices" to include all "prescription devices" (303).

When FDA attempted to inspect the records for some prescription devices, however, some manufacturers refused to comply, claiming that FDA had to first issue regulations designating prescription devices as restricted devices. The U.S. District Courts involved in resolving this issue ruled for the manufacturers, and both the First Circuit and Second Circuit of the U.S. Court of Appeals affirmed the decisions of the lower courts (30,171).

As a consequence, FDA decided to issue a regulation rather than attempt to establish through further litigation its authority to inspect records for restricted devices.

The proposed rule on restricted devices was published in October 1980 (305). However, FDA withdrew the proposed rule in November 1981, stating as its reasons: 1) comments that the current prescription device regulation was sufficient, and 2) the February 17, 1981, Executive Order 12291 on "Federal Regulation" that required Federal agencies to undertake regulatory actions only when the potential benefits of the action to society outweigh the potential costs. FDA also stated that it would use the authority for inspection of records required by the good manufacturing practices regulations, as well as the dispensing and labeling requirements of the prescription device regulations, in lieu of a restricted device regulation (309).

Banned Devices

The banned device provision of the law has been used once. Prosthetic hair fibers intended for implantation into the human scalp were banned in June 1983 (319,324).

Color Additives

FDA has not issued regulations on the color additive provisions of the amendments, but the issue has so far been limited primarily to tinted contact lenses. All contact lenses that are required to have premarket approval are also subject to the color additive provisions of the law. FDA initially approved tinted contact lenses even though the color additives had not been listed for that use before the applications were approved (317). When FDA subsequently concluded that it had to apply the color additive provision to tinted contact lenses, it decided that the least unfair method was to complete action on the pending PMAAs and to enforce the provision with future PMAAs (323). FDA is also developing proposed changes in the procedural regulations for color additives to govern their use in all applicable devices (323).

Export of Devices

FDA regulations have not had a great effect on export of medical devices, because most exported devices are those that are legally marketed in the United States and require no special FDA approval.

Most devices requiring FDA approval for export are devices that require but have not yet received premarket approval. The requirement that the importing country approve imports posed some problems because of the possibility that there might not be an official who could give approval. For that reason, FDA has accepted, in lieu of an express approval, a statement from the foreign government that it has no laws prohibiting importation of the device in question. From October 1, 1981 through March 31, 1983, 376 medical devices were approved for export, 13 devices were disapproved, and 1 previous approval was rescinded (181).

Assistance to Small Manufacturers

Both the prevalence and absolute magnitude of regulatory costs increase with establishment size, but the costs of regulations appear more unfavorable to the small manufacturer when costs are considered in proportion to establishment size (197). For example, in a limited study of 30 companies manufacturing only cardiovascular, anesthesiology, or diagnostic products, both initial and recurring costs *per employee* were higher for small plants (fewer than 100 employees) than for larger plants (100 or more employees) (17).

Small manufacturers also are more likely to need assistance in complying with the regulatory requirements. FDA's Office of Small Manufacturers Assistance has received favorable reviews by manufacturers. In a survey of medical device manufacturers, over three-quarters had heard of the office, about half of those who had heard of it contacted it, and more than three-quarters of those contacting the office had found it helpful (197).

DISCUSSION AND CONCLUSIONS

The principal provisions of the statute and FDA's activities have been catalogued above. The 1976 Medical Device Amendments attempted to regulate medical devices in proportion to a device's degree of risk through a number of pre- and postmarketing controls. The amendments placed immediate regulatory priority on significantly new devices while providing a grace period before substantial evidence of safety and effectiveness had to be provided for preamendments Class III devices and their postamendments equivalents.

Section-by-section descriptions and analyses of the major provisions of the Medical Device Amendments and their implementation by FDA were provided above to yield an understanding of the experience so far with the regulation of medical devices. The analysis also identified specific regulatory actions that have been proposed as alternatives to the current situation. However, identifying specific regulatory areas and analyzing the current approaches (and limitations) and their alternatives are not the same as developing strategies (including maintaining the status quo) for medical device regulation. The relative significance of actions that could be taken in specific areas of medical device regulation is hard to determine and justify without relating these actions to more specific strategies than the general rubric of meeting safety and effectiveness objectives at minimal regulatory costs.

In the following analysis, the principal issues that have arisen in implementing the Medical Device Amendments of 1976 are examined. Areas to be discussed include:

- the scope of medical device regulation,
- regulation of preamendments Class III devices and their postamendments equivalents,

- regulation of intermediate classes of devices,
- postmarketing controls, and
- impact of the amendments on medical device firms.

Scope of Medical Device Regulation

FDA has exempted firms from certain requirements of the 1976 Medical Device Amendments; under FDA's IDE regulations, for example, a distinction is made between "significant" and "nonsignificant" risk devices, and sponsors of investigations of nonsignificant risk devices obtain an IDE from an institutional review board rather than from FDA (see section on "Investigational Device Exemptions," above). The law also expressly permits FDA to exempt firms from notifying FDA about their intent to market selected devices, and FDA has done so for selected types of Class I devices, subject to minimal recordkeeping requirements.

The Scientific Apparatus Makers Association had petitioned FDA to drop notification requirements for Class I devices, claiming that Class I devices would still be subject to the registration requirements and surveillance under the good manufacturing practices regulations. FDA subsequently denied the petition on the grounds that the legislative intent was to make decisions on the basis of generic types of devices, and not whether or not devices were in a specific class (see section on "Premarket Notification," above).

Rather than being considered on the basis of the present statute's legislative intent, the proposal for dropping notification requirements for Class I devices could be reconsidered in a reassessment of the statute. With over 7,000 device establishments registered with FDA, listing approximately 41,500 products representing over 1,700 device types, one important question that arises is whether the scope of present device regulation is too broad. Not only could regulatory costs be excessive when information is gathered that is not going to be used, but other activities undertaken to help assure safety and effectiveness could be curtailed because of competition for funds within a limited FDA budget.

Regulation of Preamendments Class III Devices and Their Postamendments Equivalents

As of early 1984, classifications had been completed for device types in 11 of the 19 medical specialty categories, and proposed regulations, most initially issued in 1982, had been issued for those in the remaining 8 (see table 34). As preamendments Class III devices and their postamendments equivalents cannot be required to show substantial evidence of their safety and effectiveness until at least 30 months after final classification, it will be 1986 at the earliest before manufacturers of devices in the eight medical specialty categories without final classifications can be required to show that their products are safe and effective.

FDA could have expedited classification of high-priority device types within each medical specialty category instead of waiting to classify *all* devices within each category. For example, the classification process for device types that had been provisionally designated Class III could have been completed first, thereby starting the clock on the 30-month grace period.

On the other hand, the medical specialty categories for which FDA first issued final classifications (see table 34) include the categories in which most of the deaths and injuries were found in a review of the literature by the Cooper Committee before the amendments were enacted—i.e., cardiovascular (heart valves, pacemakers) and obstetrics-gynecology (IUDs). Devices in these categories continue to be the major causes of death or serious injury as reported in FDA's voluntary DEN reporting system (see section on "Postmarketing Surveillance," above). Thus, the medical specialty categories for which FDA has completed classification include those categories containing devices with the highest known risks.

Related to classification of preamendments devices is the regulation of similar postamendments devices through application of the "substantial equivalence" clause and the practice of "equivalence creep" or "piggybacking" whereby a postamendments device can be found "substantially equivalent" to another postamendments device that had been previously found to be substantially equivalent to an actual preamendments device. One issue is the safety and effectiveness of postamendments Class III devices that have been permitted to be marketed through the "substantial equivalence" route, because the preamendments devices against which they have been compared have yet to be required to show evidence of their safety and effectiveness.

After the 30-month grace period for preamendments devices expires, if FDA requires evidence of safety and effectiveness for their continued marketing, more evidence on safety and effectiveness will be available on the preamendments devices with which postamendments devices are compared. Each manufacturer of a Class III device, whether pre- or postamendments, would have to submit a PMAA if required, because FDA cannot consider the evidence of safety and effectiveness in one application when reviewing another device, even one that was previously found substantially equivalent.

As discussed earlier, FDA has initiated proceedings for some preamendments Class III devices for which the grace period has ended and which FDA has determined have the highest need for evidence of safety and effectiveness (e.g., the implanted cerebellar stimulator). Criticisms of the pace at which FDA classified preamendments devices, which determines when evidence of safety and effectiveness of preamendments Class III devices could be required, could have been muted if the classification process had been speeded up for preamendments Class III devices in all categories. Final classification of preamendments devices is no longer a major issue, however, because classifications have already been proposed for those medical specialties without final classification (see table 34), and final classification should occur soon.

The remaining issues are: 1) what type of safety and effectiveness evidence should be required for preamendments Class III devices; and 2) how the "substantial equivalence" clause should be applied by FDA. FDA, in announcing its intent to require safety and effectiveness evidence for those preamendments Class III devices it has identified as having high priority, indicated that it intended to ask for data of the type needed for premarket approval of new postamendments Class III devices (321). However, for less controversial preamendments devices, more flexibility in the types of evidence that have to be provided may be appropriate. As for the application of the "substantial equivalence" clause, other interpretations or other methods of approving postamendments Class III devices are possible (see "Policy Options" section below).

As noted above, the regulations that FDA has issued on IDEs distinguish between "significant risk" devices, for which sponsors have to receive express approval from FDA to conduct studies under an IDE, and all other Class III devices, of whose testing FDA need not be actually informed and which are considered to have approved IDEs subject to certain conditions (see section on "Investigational Device Exemptions," above). This distinction reflected express statutory authority and a decision by FDA that risks from Class III devices varied and monitoring of testing should reflect the degree of risk.

FDA has also indicated that IDEs will be made available to manufacturers of preamendments Class III devices so that they can continue to market their devices if they cannot provide reasonable assurance of safety and effectiveness when FDA requests such information. In its "Notice of Intent to Initiate Proceedings to Require Premarket Approval of Preamendments Devices," FDA has stated that within 90 days of the issuance of a final regulation, a PMAA must be filed or commercial distribution has to cease.

But an alternative for the manufacturer is to obtain an IDE and continue distribution for the limited purpose of obtaining safety and effectiveness data from clinical trials. In addition, under section 515(6) of the amendments, FDA can extend the grace period if it finds that "the continued availability of the device is necessary for the public health" (321).

The rationale for this use of the IDE is weak. Manufacturers of preamendments devices have had years to prepare to substantiate the safety and effectiveness of their devices, because the law was passed in 1976, the classification process is still not over, and there is a 30-month minimum grace period from the date of final classification.

Regulation of Intermediate Classes of Devices

For several reasons, Class II designation has probably received the most attention. First, Class II represents the important middle ground of the whole regulatory approach. Second, the majority of device types have been placed in Class II (more than 1,000 out of over 1,700; see table 34). And third, no performance standards have yet been issued.

Regardless of whether or not the 1976 statute requires, rather than permits, the use of performance standards, the fact remains that, as a practical matter, there is little possibility that standards can be formulated for the large number of device types that have been placed in Class II. If performance standards were meant to be selectively used, the designation of so many device types as Class II and the resulting perception of the futility of such an exercise have been damaging to FDA's efforts, no matter what the rationale.

At the least, the present situation points out the need for an intermediate regulatory class, the inappropriateness of mandatory performance standards as the sole or even principal method of regulation, and the need for other methods of regulating intermediate devices.

There are, of course, many ways of regulating an intermediate class of devices. The principal issues here are: 1) whether a change in the statute is needed before FDA can use other than performance standards, and 2) what types of regulatory controls could be used.

Postmarketing Controls

Postmarketing controls on medical devices are of two types: 1) removal from the market or restrictions on the sale, distribution, or use of designated devices; and 2) postmarketing surveillance of the clinical experiences with medical devices.

FDA can remove a device from the market by requiring repair, refund, or replacement; by banning it; or by revoking any approval to market the device. There are two types of restrictions on the sale, distribution, or use of a device. The first is a restriction to prescription sale or use, applied when adequate labeling for lay use cannot be written or when special skills or training are required, such as diagnosing a disease or condition or prescribing for treatment. The second is a restriction based on other conditions FDA may prescribe in regulations in order to provide reasonable assurance of the safety and effectiveness of the device.

The restricted device regulations were withdrawn by FDA with the explanation that the prescription device regulations were adequate. In addition, Executive Order 12291 requires that Federal agencies undertake regulatory actions only when the potential benefits outweigh potential costs. However, in the original proposed regulation, FDA had stated that (305):

> . . . the current determination that a device is a "prescription" device is quite subjective. Often, the determination is made by the manufacturer.

FDA therefore proposed the restricted device rule to make these criteria more objective.

FDA also stated in its withdrawal of the proposed restricted device rule that it would use its inspection authority under the good manufacturing practices regulations to inspect manufacturers' records on these types of devices for information on such matters as deaths and injuries (309). But the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee observed that (338):

> . . . most of the general controls . . . are geared toward ensuring that finished devices, when ready for use, will be free from defects, safe and effective. Restriction, on the other hand, can address problems with a device once it is in use. It deals with the risks that practitioners, technicians, or others who employ the device are doing so improperly due to inadequate training, experience, facilities, or instructions.

These issues—use of existing sources of information on deaths and injuries, and problems arising from improper use of medical devices rather than from improper manufacture—have also been involved in the debates on the types of postmarketing monitoring activities that should be conducted.

One of the expressed reasons why mandatory device reporting regulations have been held in abeyance was to examine whether the complaint files which are required under the good manufacturing practices regulations could partially or completely substitute for the mandatory device reporting regulations. As described earlier, the examination had been completed by early 1984, with the conclusion that the good manufacturing practices complaint files are not adequate substitutes for mandatory reporting (257).

On the question of improper use, the General Accounting Office has recommended that FDA's voluntary DEN reporting system be revised so that information is included on the scope and nature of device problems caused by user error and inadequate maintenance; that the data be analyzed to identify special problems, areas where problems might be concentrated, and trends; and that the results be used to aid in developing solutions. FDA responded that these recommendations would be taken into consideration and that possible actions would include implementing educational programs or restricted use criteria (331).

Thus, FDA may eventually issue restricted device regulations, subject to the current administration's position on deemphasizing regulatory approaches and its preference for voluntary initiatives. Furthermore, efforts may be made to upgrade the voluntary DEN system and disseminate that information to educate users about potential hazards.

Impact of the Amendments on Medical Devices Firms

The preceding analyses examined individual provisions of the 1976 Medical Device Amendments and their implementation by FDA. A broader issue is the impact of the amendments on the medical devices industry. Information available on the impact of the law reflects regulatory implementation by FDA and understanding of the law by device firms in the first few years following passage of the statute. In evaluating this impact, it is important to keep in mind that some sections of the amendments have been implemented fully, some partially, and some have yet to be addressed.

Two studies that FDA conducted to establish "baseline conditions" in order to track changes that occur in the future were summarized earlier, based primarily on 1977 data (391,392). These studies showed that the "medical devices industry" is quite heterogeneous. There is a clear separation of the industry into medical device versus diagnostic testing firms, with little overlap between manufacturers of either type of product.

The medical device portion of the industry is further separable into establishments that are highly specialized and those that manufacture devices in several areas. Sixty-four percent of manufacturers made devices in only one device area. Highly specialized areas include dental, ophthalmic, and radiological devices.

Each device type is made by an average of nine different manufacturers, but this measure of "product availability" or "concentration" in the industry is related to the class of the device. Class I device types averaged 13.1 manufacturers per type; Class II, 7.9 manufacturers; and Class III, 4.5 manufacturers. Devices made by only one or two manufacturers ("exclusive" devices) comprised 28 percent of all device types and followed a similar pattern. Only one or two establishments were manufacturing 41 percent of the Class III device types, compared to 28 percent of Class II device types and 24 percent of Class I device types.

Large establishments were more likely to make: 1) more device types, 2) an "exclusive" device, 3) a Class III device, or 4) a "critical" device (defined by FDA as requiring more rigorous controls in the manufacturing process).

These findings lead to the following observations. First, the distinction between firms that manufacture diagnostic tests and firms that manufacture other medical devices probably reflects the "catchall" nature of the 1976 Medical Device Amendments, which essentially authorized Federal regulation over all medical products that are not drugs or biologics. One question is the appropriateness of regulating such distinctly different products in a similar manner. For example, Class III medical devices are generally those that are implanted or have life-support or life-sustaining functions, and criticisms of FDA's application of the law to devices of this nature have been raised when FDA has chosen *not* to place some of these types of devices in Class III (253).

On the other hand, diagnostic tests pose few direct risks, but some have been placed in Class III because defective tests could lead to erroneous treatment (or no treatment), which in turn could result in harm to patients. The underlying questions are whether the law's scope and application are appropriate, and if not, whether regulation of diagnostic tests and other medical devices can be addressed differentially under the present law or whether new legislative remedies should be explored.

Second, it should be remembered that the findings that devices in higher regulatory classes have fewer manufacturers per device type and that larger manufacturers are more likely to manufacture devices in a higher regulatory class represent the situation that was already present before the amendments were implemented. Classification under the 1976 amendments did not *cause* but might be expected to *reinforce* this situation, especially for Class III devices, because of the higher costs associated with approval.

FDA also commissioned a survey conducted in the fall of 1981 of medical device manufacturing establishments that had been registered with FDA in September 1980 (197). The surveyors concluded that there was no evidence that the amendments raised barriers to market entry, reduced innovation, or adversely affected investment, sales, or employment. For example, one of the survey's conclusions, based on information provided by the surveyed manufacturers, was that there was no evidence that patent activity had measurably declined since the Medical Device Amendments were enacted in 1976.

Figures 2 and 3 provide a more comprehensive picture of medical device patent activities, summarizing patent applications with the U.S. Patent Office between 1968 and 1979. Patent applications on "low-technology" devices such as bandages, receptacles, eyeglass frames and lenses began leveling off just prior to the 1976 amendments. But applications for "high-technology" devices such as implants, dialysis machines, respiratory devices, and cardiovascular devices continued to increase throughout the decade (see app. D)

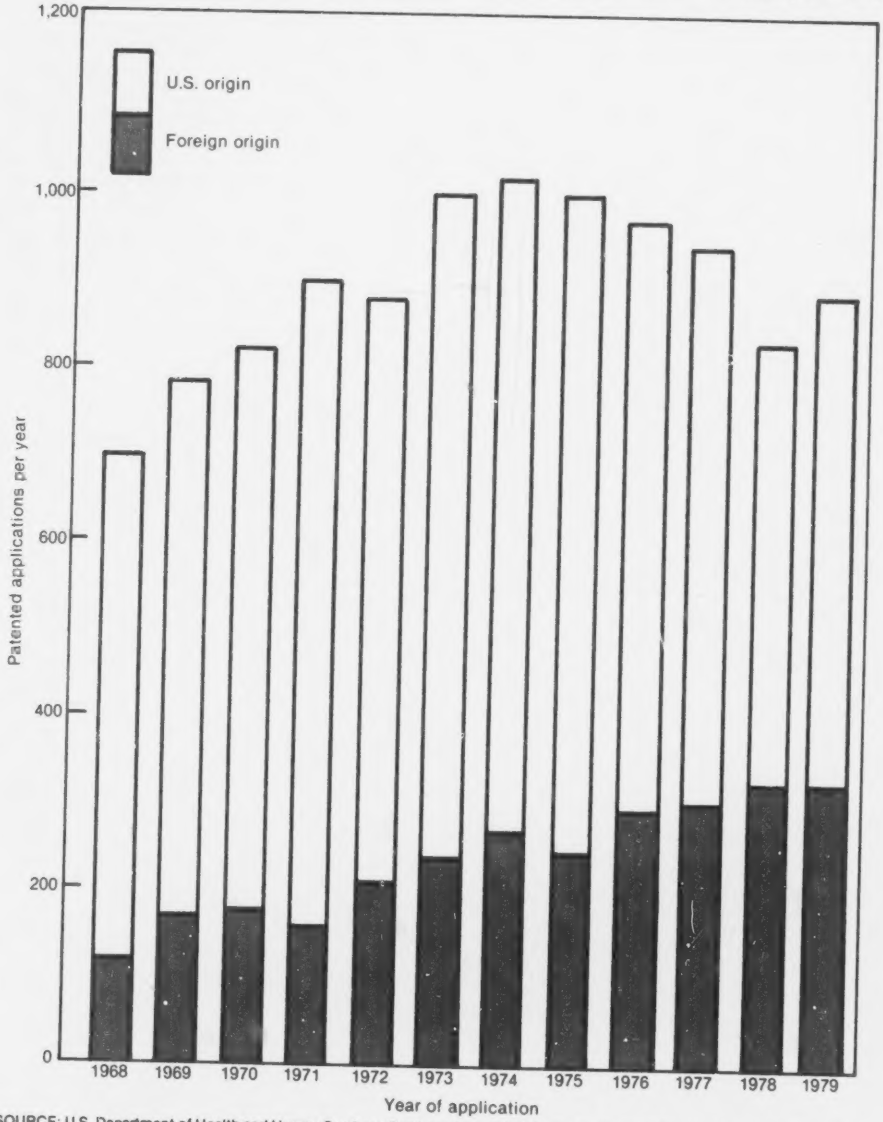
The 1981 survey commissioned by FDA found that a third of all manufacturers had entered the medical device field *after* the 1976 statute (197). Most manufacturers reported increases in domestic and foreign sales, research and development (R&D) activities, and the number of new devices introduced since the amendments. Fifty-one percent were more profitable and only 27 percent less profitable than they had been prior to passage of the amendments, and 80 percent were optimistic about doing business in medical devices during the next decade.

The survey also found that significant R&D activities were common traits in medical device firms—whether they were large, medium, or small—and that the introduction of significantly new medical devices had been just as common for small firms as for large firms (197). But when the survey was conducted in the fall of 1981, only a quarter of small establishments (1 to 9 employees)—as compared to 63 percent of establishments with over 500 employees—reported that they would consider developing and marketing a Class III device. The surveyors concluded that Class III designation appears to be more likely to discourage small establishments than large establishments from developing new devices, but observed that opinions do not necessarily translate into behavioral differences. They pointed out that 8.4 percent of establishments were manufacturing Class III devices and that a higher percentage of manufacturers would continue developing Class III devices.

Somewhat in contrast with the overall optimistic picture of the industry just presented were manufacturers' answers to the survey question of the impact of the Medical Device Amendments (197). Nearly half (46 percent) stated that Federal regulation had been a major problem for them, and 21 percent stated that regulation was the single most serious problem. However, although most manufacturers wanted changes in the regulations, they did not believe (53 percent) that device regulation should be abolished, and the vast majority (80 percent) believed that at least implants and life-support or life-sustaining devices should be strictly regulated.

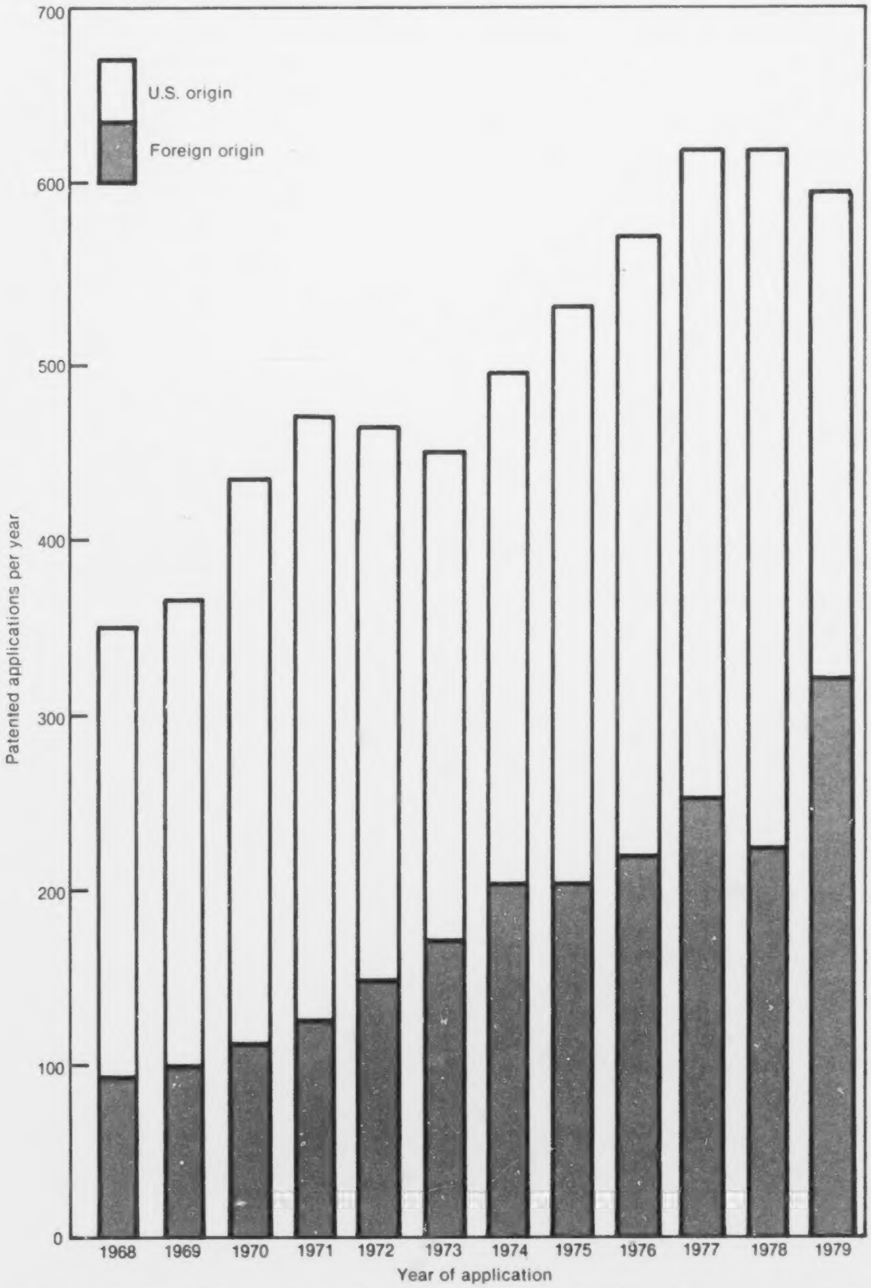
The specific problems associated with regulation under the 1976 amendments were varied (197). One problem reported by a substantial

Figure 2.—U.S. Patent Applications for Low-Technology Medical Devices, 1968-79



SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, Rockville, MD, compilation of unpublished data from the U.S. Patent and Trademark Office, December 1983.

Figure 3.—U.S. Patent Applications for High-Technology Medical Devices, 1968-79



SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, Rockville, MD, compilation of data from the U.S. Patent and Trademark Office, December 1983.

number of manufacturers in the 1981 survey was the cost of compliance. In order to meet the regulatory requirements, 64 percent either added new employees, purchased new equipment, or increased outside purchases. Absolute costs increased with establishment size, but when adjusted for establishment size, smaller manufacturers had relatively higher costs per employee in meeting the regulatory requirements.

Another problem reported by a significant number of manufacturers was in understanding what to expect from FDA in meeting the regulatory requirements. Of particular interest is the correlation between manufacturers' attitudes toward FDA and their understanding of the regulations. Of those manufacturers who said they fully understood the regulations, about half (51 percent) gave FDA a positive rating, and 71 percent stated that the regulations were effectively protecting the public. The Office of Small Manufacturers Assistance was one FDA information source that was positively received by the industry, but difficulty in understanding the regulatory requirements was still a major problem and fell disproportionately on small manufacturers. Thus, a particular priority for regulatory reform was in special efforts to improve manufacturers' understanding of the device regulations.

Despite the negative opinions by manufacturers regarding regulation, majorities still reported that registration, product listing, product classification, labeling requirements, premarket approval, and IDEs had no effects on their establishments (197). Seventeen percent of manufacturers even reported that good manufacturing practices have been of help to them.

Under the 1976 amendments, difficult and complex precedent-setting decisions have been made on a diversified industry that was not previously subject to a great deal of FDA regulation. In general, the 1976 Medical Device Amendments have not had a significant negative impact on the manufacturers of medical devices. Particular segments of the industry may be more affected than others, however, and compliance costs affect small manufacturers relatively more than they do large manufacturers.

In the contact lens industry, the issues of the costs of complying with regulations and small manufacturers' entry into the market have converged (see discussion under "Reclassification of Devices" section, above). Class III designation of new types of contact lenses (soft lenses, gas-permeable lenses) has made it difficult for many small companies to gain early entry because of the costs of gathering clinical evidence on safety and effectiveness. But there has not been a unified front by the contact lens industry against Class III designation. Rather, large firms that already have market approval have tended to resist reclassification from Class III to Class I or II. At issue in this instance is competition between first entrants into the market and subsequent manufacturers. The public policy goals that are at odds are rewarding companies that first succeed in getting innovations on the market versus achieving greater availability of products of a particular type, with price competition as one result.

Throughout the medical devices industry, one of the impacts of medical device regulation has been uncertainty over the regulatory requirements. This situation, in retrospect, is understandable, given the fact that the implementation

Photo credit: Bausch & Lomb SOFLENS, Professional Products Division

The new generation of contact lenses, such as the soft contact lens show on the left, are subject to the full premarket approval process of the Food and Drug Administration. The older types of hard contact lenses, such as that shown on the right, no longer have to go through the full premarket approval process.

of some provisions of the law has not been initiated or completed and the fact that the majority of devices have been placed in Class II, despite inability to proceed with the statutory intent of regulating this class of devices through performance standards.

Conclusions

During the 8 years since the Medical Device Amendments of 1976 were enacted, the medical devices industry has continued to grow, and while regulatory costs have been incurred, regulation has generally not had a significant negative impact on the industry. A large part of the industry's development may be due in part to FDA's implementing the 1976 law in ways that would make market entry easier—as in use of the 510k premarket notification and a finding of "substantial equivalence" as the predominant route for devices to be released for marketing—and in part to FDA's not implementing or implementing slowly some of the law's provisions. The situation for industry may change if FDA implements all of the provisions of the amendments, or as new medical devices are developed that make it harder over time to use the "substantial equivalence" route to market devices.

Several provisions of the amendments that are targeted at specific risk *categories*—such as those pertaining to the safety and effectiveness of preamendments devices, regulation of Class II devices, and monitoring of devices once they are on the market—have yet to be fully implemented or addressed. Yet there is little information that *actual* risks are systematically occurring or not being addressed by FDA's choice of priorities in implementing the amendments.

This paucity of information on actual risks can be interpreted in two ways, based on opposing assumptions. First, it might be taken as an indication that hazards are in fact low, that the current application of the amendments is satisfactory, and that it is not necessary to implement all of the law's provisions. An alternative interpretation is that the paucity of information on risks is a deficiency in itself—one that the amendments attempted to address—and that a lack of information on risks is a problem that needs to be addressed.

The Medical Device Amendments provided more effective methods for dealing with fraudulent devices, and the increasingly complex nature of "high-technology" medical devices was one of the imperatives for developing premarket screening and testing requirements. Public policy in these two instances was not primarily dependent on quantifying the number of injuries currently caused by medical devices. In the case of fraudulent devices, the amendments provided more effective tools for removing these devices from the market. For "high-technology" devices, the amendments attempted to anticipate and minimize potential risks associated with their use through pre- and postmarketing controls. Realistically, however, it might be expected that debates over how and to what extent medical devices should continue to be regulated will focus on the costs to industry versus (lack of knowledge of) the extent of risks associated with medical devices.

In sum, 8 years after the Medical Device Amendments of 1976 were enacted, the medical device industry has incurred regulatory costs but continues to prosper in general; major sections of the law remain partially or not implemented, and there do not seem to be any obvious, major risks that are not being addressed, a situation that may reflect either a lack of significant risks or lack of knowledge of significant risks that do exist.

POLICY OPTIONS

Most of the attention that has been focused on medical device regulation since the enactment of the 1976 Medical Device Amendments has been oriented toward questions such as whether a particular provision of the 1976 law has been implemented, whether its implementation has been compatible with congressional intent, and whether the provision worked in practice as it did in concept (331,338). A range of options proposed for specific issues that the current law was designed to address is provided below. Areas of the law to be specifically addressed include:

- evaluating the safety and effectiveness of preamendments devices and their postamendments equivalents,
- developing performance standards for Class II devices,
- reviewing postmarketing activities and controls, and
- assisting small manufacturers of devices.

Beyond developing options on specific provisions of the law, however, there is the question of how specific actions fit within an overall regulatory framework. Various overall regulatory approaches are presented in the first three options below.

Scope of Medical Device Regulation

Option 1: Continue the basic framework and intent of the 1976 Medical Device Amendments and make adjustments in implementation or wording of the specific provisions of the law.

A judgment could be made that the basic framework and intent of the 1976 amendments remains appropriate and that the law's implementation by FDA should proceed, subject to modifications in the wording or implementation of specific provisions of the law that reflect judgments on the appropriate balance between methods of ensuring safety and effectiveness and the costs associated with these methods.

FDA, in implementing the 1976 law, has had to develop a set of priorities so that its limited resources could be efficiently applied. Congress could provide more direction to FDA on what it considers priority issues and what orientation it considers appropriate within a particular regulatory area. Setting such priorities would entail weighing benefits to consumers from reducing risks and ensuring efficacy versus costs to the industry from regulatory requirements. Examples of priority areas might include approval of new devices, particularly Class III; safety and effectiveness of preamendments Class III devices; selective monitoring and controls over marketed devices; and development of better information on device-associated risks.

Congress could also provide direction within each priority area on the extent of its concern about ensuring safety and effectiveness versus minimizing barriers to market entry. Approaches to balancing safety and effectiveness versus ease of marketing are reflected by the variation in the types of safety and effectiveness evidence that could be required for preamendments Class III devices and in whether FDA or device manufacturers should bear the burden of proof (see Options 4, 5, and 6).

A different strategy from focusing on which provisions of the law should be emphasized would be for Congress to determine which aspects of the current law do *not* have high priority. The exemption of devices from some of the law's requirements through the use of FDA's discretionary authority has been previously discussed. FDA has exempted manufacturers of some Class I device types (e.g., specimen containers) from having to notify FDA when they intend to market their devices and from most of the recordkeeping requirements of the good manufacturing practices regulations. In the regulations on IDEs, FDA makes a distinction between "significant risk" and "nonsignificant risk" Class III devices and requires different procedures for the two. Also mentioned earlier was a petition to FDA from the Scientific Apparatus Makers Association, subsequently denied by FDA as being against legislative intent, to drop 510k notification requirements for *all* Class I devices.

Option 2: Revise the 1976 Medical Device Amendments to reflect the status quo with regard to FDA's implementation of the law.

Although the issuance of mandatory performance standards for Class II devices has proved not to be feasible and FDA has yet to complete the implementation of several other provisions of the 1976 law, obvious, systematic deficiencies in the safety and effectiveness of medical devices have not been apparent. One approach, therefore, might be to recognize the two-tiered regulatory approach that has been applied to medical devices rather than the three-tiered approach originally built into the law.

More flexibility could be obtained through the kinds of controls identified previously to augment or replace Class II performance standards (see Option 13), but the bedrock of the law could be limited to: 1) general controls for all devices, and 2) premarket approval requirements for a limited number of devices, such as implantable or life-supporting devices. Other current provisions could also be modified or deleted. For example, review of preamendments devices could be limited to high-priority device types, the approach that FDA is currently taking.

Option 3: Revise the 1976 Medical Device Amendments to exclude certain device types from regulation.

In the previous option, revisions in the law would be guided by FDA's implementation of the law to date. In addition to or in place of that option, Congress might choose to consider statutory exclusions of some device types.

Statutory modifications could be guided by focusing on risks, such as the proposal to exempt Class I devices from notification and recordkeeping requirements, or by focusing on the variety of medical products currently under the jurisdiction of the amendments, such as the question of whether it is appropriate to regulate diagnostic tests in the same manner as other types of medical devices.

Regulation of Preamendments Devices and Their Postamendments Equivalents

The 1976 amendments provided a 30-month grace period after final classification before evidence of the safety and effectiveness of preamendments Class III devices would be required by FDA. For these devices, two issues that remain are what type of evidence has to be presented and when that evidence has to be provided to FDA. In part, these issues are important because of the widespread use of the "substantial equivalence" method of gaining market entry for postamendments devices. As previously discussed, a finding of substantial equivalence will be made if a new device does not differ markedly as to materials, design, or energy source, and if there is no significant difference with regard to safety and effectiveness. As yet, however, there is no requirement to provide safety and effectiveness evidence on the preamendments devices with which new devices claimed to be their substantial equivalents are compared.

In addition, FDA's Office of General Counsel does not consider a finding of "substantial equivalence" an approval. A device is considered approved once a determination is made that it is safe and effective. The 510k method of obtaining FDA's permission to market a device is basically a determination that the device is substantially equivalent to a preamendments device, and FDA has no choice but to allow it to be marketed; it is not a determination that the device is safe and effective (464).

ISSUE:

What evidence of safety and effectiveness should be required of preamendments Class III devices?

Option 4: Continue FDA's current approach of emphasizing safety and effectiveness evidence for high-priority preamendments Class III devices.

Under FDA's current policy as represented by this option, preamendments Class III device types with questionable safety and effectiveness or with relatively high risks will be addressed by FDA first, using expert opinion and publicly available literature. This approach can be viewed as a reasonable allocation of FDA's limited resources, although FDA has to gather and review information to set areas of priority, and developing the information can be very resource-intensive for FDA.

Option 5: Limit through legislation requirements for evidence of safety and effectiveness of preamendments Class III devices to device types that have specific problems associated with them.

This option would codify FDA's current approach so that FDA would *have* to identify preamendments Class III device types with problems before it could require evidence of safety and effectiveness. Other preamendments device types would be presumed to be safe and effective, subject to development of new information. As in the previous option, this approach could be resource-intensive for FDA because the agency would have to gather evidence to identify problem devices. Legislating this approach instead of relying on FDA's discretion would reduce uncertainty and make it explicit that all preamendments Class III devices will not eventually have to show evidence of safety and effectiveness.

Option 6: Encourage FDA to accept evidence of safety and effectiveness such as reviews of the literature and expert opinion, in lieu of clinical evidence, for preamendments Class III devices.

In the two previous options, the safety and effectiveness of preamendments Class III devices would in effect be presumed, and FDA would develop information to counter that presumption before initiating actions. In this option, the burden of providing FDA with evidence of safety and effectiveness would continue as now to rest with the manufacturers, but the range of acceptable types of evidence would be greater. This approach would enable FDA to screen all device types or a greater number than would the two previous options, and the screening process might then be used by FDA to target problem devices.

A variation of this option would be for FDA to start with the presumption that clinical data on devices are required but allow manufacturers to overcome that presumption with evidence gained from general use of these types of devices.

ISSUE:
When should safety and effectiveness evidence be required of preamendments Class III devices?

Option 7: Continue FDA's interpretation that the end of the 30-month grace period after final classification establishes the earliest date that FDA can require safety and effectiveness evidence on preamendments Class III devices.

Because the 30-month grace period establishes the earliest date on which the agency can act, FDA has begun the process of requiring safety and effectiveness evidence for only a few "high-priority" preamendments Class III devices. FDA's priority-based review is dictated by the limited resources available to FDA and the resulting difficulty in calling for evidence of safety and effectiveness for all preamendments Class III devices as their grace periods expire. Thus, the issue of *when* such evidence will be required is related to the question of what *kinds* of evidence will be acceptable (see Options 4, 5, and 6).

Option 8: Establish the end of the 30-month grace period after final classification as the time when FDA has to call for safety and effectiveness evidence on preamendments Class III devices.

This option could be legislated, but its desirability depends on whether FDA takes other approaches to ensuring safety and effectiveness as discussed above and on the resources FDA could devote to preamendments devices relative to other provisions of the law. For example, if FDA takes the approach in Option 6 of accepting a greater range of evidence to screen for problem devices, this option would be much more reasonable to implement than under current conditions, in which FDA has assumed responsibility for identifying problem areas.

Option 9: Prohibit use of the IDE to extend the grace period for preamendments Class III devices that have been required to show evidence of safety and effectiveness, except when no acceptable alternatives are available.

The grace period for many preamendments devices had not ended or had not even begun as of early 1984, 8 years after the amendments were passed. Given this extended period of "notification," there seems little justification for making IDE routinely available to preamendments device manufacturers. Possibly, however, IDEs could be made available on a case-by-case basis. Routine use of the IDE to continue limited distribution of preamendments devices would be less of an issue if other types of evidence of safety and effectiveness, such as literature reviews and expert opinions, were accepted.

Except for those options specifically calling for legislation, all of the options pertaining to preamendments Class III devices could be implemented under the existing statute. However, Congress could mandate a particular approach through legislative changes.

ISSUE:

Does the "substantial equivalence" method of entering the market for postamendments medical devices need to be revised?

The 1976 Medical Device Amendments require that any postamendments device not found "substantially equivalent" to a preamendments device be automatically classified in Class III, with subsequent opportunity to petition for reclassification of the device in Class I or II. The "substantial equivalence" clause of the 1976 law was meant to make a regulatory distinction between those postamendments devices that are modifications of commercially available devices from those that are truly new devices.

Because of the costs and delays in approval associated with the reclassification process, however, manufacturers of postamendments devices have had incentives to seek a finding of "substantial equivalence" rather than reclassification so that they can market their devices much sooner. Much less information is needed to successfully claim that a postamendments device is substantially equivalent to a preamendments device than to gain approval through the premarket approval process. In fact, the lack of information on the safety and effectiveness of preamendments devices raises questions about how determinations of substantial equivalence can be made.

Option 10: Retain existing procedures for determining "substantial equivalence."

As previously explained, FDA has begun to call for safety and effectiveness evidence on high-priority preamendments Class III devices, and once that evidence is presented and evaluated, there should be a substantive basis for comparing these devices with postamendments devices determined to be substantially equivalent. But the process will take years and may be selective rather than including all preamendments Class III devices.

On the other hand, the "substantial equivalence" clause has been a convenient method for device manufacturers to get their products onto the market quickly But as new generations of postamendments devices diverge more and more from their preamendments antecedents, it will be harder for manufacturers to use the substantial equivalence method of market entry. It will also be harder to practice "piggybacking," in which a postamendments device is compared to another postamendments device and, through a chain of other postamendments devices, eventually compared to a preamendments device.

More immediately, FDA's Office of General Counsel has stated that such "piggybacking" is not authorized by the amendments (464), and if the practice of piggybacking ceases, more postamendments devices will eventually be placed in Class III, and their manufacturers will have to go through the full premarket approval process or petition FDA for reclassification.

Option 11: Eliminate automatic classification into Class III of postamendments devices that are not found substantially equivalent to preamendments devices, and allow FDA to place a device in the appropriate class at the time of notification.

Automatic classification into Class III of postamendments devices that are not found substantially equivalent to preamendments devices serves as a second screen in the regulation of post-1976 devices. The first screen is a determination of whether or not a device is "substantially equivalent" to a preamendments device. The second screen, with automatic classification into Class III, is a presumption that any device that is not substantially equivalent needs full premarket approval, unless the manufacturer successfully petitions FDA for reclassification in Class I or Class II. Under this option, the burden of responsibility of coming forth with evidence that rebuts initial Class III designation could remain with device manufacturers, but manufacturers could be allowed to present this evidence for classification at the time of notification. This change should reduce current incentives to claim "substantial equivalence."

Option 12: Develop approaches for reviewing new devices that are different from those for reviewing modifications of commercially available devices.

Eliminating automatic Class III designation of postamendments devices that are not found substantially equivalent to preamendments devices might serve to bring out the distinction between modified and new devices that the "substantial equivalence" clause was originally meant to provide. GAO has recommended another approach, eliminating the "substantial equivalence" clause so that all Class III (but not Class I or II) postamendments devices have to go through premarket approval. (Automatic Class III designation for non-substantially equivalent postamendments devices could also be eliminated so that new devices that would more appropriately be put into Class I or II would not have to go through the superfluous step of reclassification.) In general, then, the difference in approach could be between pre- and postamendments devices as originally intended, or between Class III pre- and postamendments devices, where the difference in regulatory requirements is most pronounced.

Regulation of Class II, or Intermediate, Devices

More than 1,000 of the 1,700 device types have been placed in Class II. The unanimous opinion, however, is that except for a small number of device types, performance standards cannot be developed in a timely fashion. Thus, if an intermediate class of regulation is still needed, performance standards will have to be replaced by other types of regulation between Class I and its good manufacturing practices requirements and Class III and its premarket approval requirements.

Option 13: Give FDA legislative authority to use available methods in addition to performance standards to regulate Class II devices.

An obstacle to the use of methods for regulating Class II devices other than performance standards has been the question of whether or not the law *requires* the use of performance standards. GAO has in fact suggested that the law be revised to give FDA the authority to make a device-by-device determination of when performance standards are needed (331). Although the use of performance standards may not be mandatory, a change in the statute clearing up the ambiguity might be useful in setting into motion substantive efforts to use other approaches, instead of continuing to focus attention on the unrealistic expectation that so many performance standards can be developed.

FDA has suggested using a combination of voluntary standards, user education, and other existing controls to regulate Class II devices (387). Previously identified controls include revoking any approval to market a device, banning the device, or requiring repair, refund, or replacement, and the prescription and restricted device provisions. If the legality of using available approaches in place of performance standards is upheld or the use of these remedies legislated, a three-tiered regulatory system for medical devices can be put in place. Rather than a Class II with mandatory controls, however, there would be specific devices (Class I or Class III) for which additional controls could be stipulated (e.g., prescription or restricted devices), and device-by-device determinations of the applicability of these other controls.

Option 14: Legislate an additional category of Class II devices to be regulated through methods other than performance standards.

The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce has suggested that performance standards be retained for Class II and that a Class IIA be formed on which greater controls (e.g., restrictions under the restricted device clause, increased mandatory device experience reporting, and adoption of performance specifications against which the device must be tested periodically) are imposed (338).

This option is similar in effect to the previous option, the principal difference being that this option involves legislating an explicit, additional category of Class II devices and retaining mandatory performance standards for some devices. Also, this option would leave less discretion to FDA in determining which devices should be regulated and how they should be regulated.

Option 15: Encourage FDA to reclassify most Class II device types into Class I or III and to continue to develop performance standards for the remaining Class II devices.

Rather than being regulated through performance standards, medical devices receiving Class

II designation are currently being regulated by FDA as though they were Class I devices. A partial approach to the problem might be to screen current Class II devices to see whether some of them could be placed in Class III. This issue was raised by the Health Research Group in the case of General and Plastic Surgery devices, when FDA proposed placing seven implantable device types (including artificial ears, noses, and chins) in Class II rather than Class III (253).

The burden of regulation under Class III for reclassified Class II devices might not be onerous. FDA already differentiates between "significant risk" and "nonsignificant risk" Class III devices in its IDE regulations, and FDA could develop different levels of evidence for safety and effectiveness of the types previously discussed under options for preamendments Class III devices (Option 6).

Postmarketing Monitoring and Controls

The lack of information on risks associated with the use of medical devices can be viewed either as evidence that such risks are not extensive and that more vigorous device regulation is not needed, or instead as an indication that monitoring systems should be improved to yield more information before risks are discounted. Identifying problems is crucial in determining which devices may need additional controls and what types of controls should be applied. Thus, improved information on risks would be helpful both for determining the scope of the problems that regulation could address and in applying the appropriate types of controls.

Option 16: Require FDA to develop better systems for monitoring and providing information on risks associated with devices.

FDA is reportedly ready to make final its regulations on mandatory device experience reporting by manufacturers, subject to the Office of Management and Budget's approval (257). GAO has suggested that FDA's voluntary reporting system, the Device Experience Network (DEN), be revised so that information is included on the scope and nature of device problems caused by user error and inadequate maintenance; that the data be analyzed to identify special problems and trends; and that the results be used to aid in developing solutions (331). GAO is also initiating a comprehensive exploration of postmarketing surveillance activities and their potential applications (300).

Thus, there is a gradual movement toward better identification of, and faster and more targeted responses to, device risks. The process might be accelerated by legislating mandatory device experience reporting instead of continuing with the permissive language contained in the statute.

Option 17: Encourage FDA to selectively apply postmarketing controls to regulate Class II devices.

Postamendments controls could be applied to a new class of Class II devices or left to be applied by FDA on a device-by-device basis (see Options 13, 14, and 15). A reconstituted three-tiered classification approach would result. Minimal regulation would apply to the lowest class of devices through the good manufacturing practices regulations. An intermediate class of devices (Class II) would be represented by those devices that have additional controls (prescriptions, restricted devices, postmarket controls) applied to them of the types identified in addition to the good manufacturing practices requirements. The highest regulated class of devices would have to meet premarket approval requirements and might have additional controls imposed on their marketing.

Assistance to Small Manufacturers

The 1976 amendments contained a provision to help small firms through the regulatory process by establishing an Office of Small Manufacturers Assistance. Two other steps could aid small firms in manufacturing Class III devices: 1) where appropriate, Class III devices could be down-classified as soon as possible; and 2) small firms could be given assistance in developing the safety and effectiveness evidence necessary for Class III device approval.

Option 18: Develop additional mechanisms to help small firms through the regulatory process.

Option 18A: Encourage FDA to use publicly available information as soon as possible to down-classify Class III devices.

FDA could take the initiative in identifying Class III devices of significant importance to public health and could monitor their use. Thus, publicly available information could be accumulated at the earliest possible time and down-classification could be initiated.

Option 18B: Develop a "broker" mechanism between small firms with promising devices and clinical investigators capable of performing the tests necessary to gather safety and effectiveness data in support of the premarket approval application for Class III devices.

Although Option 18A might help small firms gain approval for medical devices that are already on the market, it would not help small firms that want to be among the first to have their devices approved for marketing.

There is some precedent for a broker function, although there might be questions of conflict-of-interest if FDA assumed the role. One precedent, for example, is the past and continuing collaboration between commercial sponsors and specific institutes at the National Institutes of Health in performing clinical trials for potentially significant new drugs to meet FDA's requirements of clinical testing for premarket approval. Another precedent is the Federal promotion of "orphan" medical products, in which Federal funds are used to support clinical trials for promising products that have a limited market, such as drugs for rare diseases. Thus, as a broker, FDA could maintain a registry of potentially marketable devices and provide it to interested parties.

6.

Regulation of the Providers of Medical Devices

For the general run of consumer goods, the buyer is necessarily an amateur while the seller is a professional.

—*Joan Robinson*

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6.

Regulation of the Providers of Medical Devices

INTRODUCTION

Regulation in health care has developed because of certain conditions that set the health care field apart from many others. Large segments of the American public do not have sufficient medical knowledge to make informed decisions about their health care. To a significant extent, therefore, especially in the case of sophisticated procedures and unusual medical conditions, patients must rely on the judgment of physicians or other health care professionals. Furthermore, as described in chapter 3, the system of third-party financing for medical care that has evolved in this country has fostered the uncritical adoption and sometimes excessive use of medical technologies, including medical devices. Such adoption and use, in turn, have contributed to a rapid rate of increase in Federal expenditures under programs such as Medicare and Medicaid and in national health care expenditures generally.

Chapter 5 discussed the Food and Drug Administration's regulation of drug and device manufacturers to protect the public from unsafe and ineffective drugs and medical devices. This chapter examines regulations pertaining to the health care institutions and individuals—i.e., hospitals, nursing homes, home health agencies, ambulatory surgical centers, clinical laboratories, and others—that provide or use major medical equipment, such as computed tomography (CT) scanners, or smaller devices, such as sutures or splints.

Various Federal and State regulatory programs affect the providers of medical devices. As noted in the discussion that follows, regulation of health care providers has been undertaken with several objectives in mind:

- that people receive care of acceptable quality,
- that rising expenditures on health care are controlled, and
- that the distribution of medical facilities is equitable.

This chapter analyzes the impact of Federal and State regulation of providers on adoption and use of medical devices in specific health care delivery sites. It also discusses interactions among the regulations and proposed changes. Although decisions to adopt and use medical devices are typically made by physicians, most of the regulations discussed in this chapter affect physicians only indirectly.

FEDERAL REGULATION OF PROVIDERS

At the Federal level, providers of services to Medicare beneficiaries are regulated through conditions of participation, section 1122 of the Social Security Act, and professional standards review organizations (PSROs) (currently being replaced by the utilization and quality control peer review organizations, PROs). Providers are also regulated under State laws required by the Federal health planning program.

Federal Regulation of Providers Under Medicare

Designers of the Medicare program wanted to ensure that the Federal Government paid for good quality care for elderly and disabled people eligible for benefits under this program (107), and conditions of participation for providers were adopted at the outset of the program to attain a satisfactory level of quality. As the program was implemented and costs rose, cost containment also became an issue. Thus, in the Social Security Amendments of 1972 (Public Law 92-603), both to help ensure beneficiaries' access to quality medical care and to help contain costs, Congress created the PSRO program and added section 1122 to the Social Security Act. Along with conditions of participation, PSRO review of the utilization and quality of services provided to Medicare beneficiaries and section 1122 review of capital expenditures are described further below.

Conditions of Participation

Conditions of participation are requirements that must be met by hospitals and other providers in order to receive payment for treating Medicare or Medicaid patients. The purpose of the conditions is to assure a basic level of quality of the medical care for which the Federal Government pays (107). The conditions of participation for hospitals are similar to the voluntary standards promulgated by the Joint Commission on Accreditation of Hospitals (JCAH) (see box L) or the American Osteopathic Association. About 5,200 hospitals accredited by JCAH or the American Osteopathic Association are automatically considered in compliance with Medicare quality standards. However, an additional 1,495 hospitals are not accredited by either of these organizations but do participate in Medicare or Medicaid (315).

Some conditions of participation for providers list specific medical devices whose availability is required. The lists of devices in conditions of participation are generally not extensive or exhaustive, but instead allow providers flexibility in deciding which services to make available. Hospital operating suites, for example, must have the following equipment available: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, thoracotomy set, and tracheostomy set (42 CFR 405.1031 (a) (II)). Freestanding ambulatory surgical centers must provide laboratory and radiologic services that include, but are not limited to, such medical devices as surgical dressings, splints, casts, appliances, materials for anesthesia, and diagnostic or therapeutic services directly related to the provision of surgical procedures (42 CFR 416.46 (c)).

The conditions of participation have not undergone any substantial revision since Medicare began operating in 1966. Revisions proposed by the Department of Health and Human Services (DHHS) in January 1983 would make the conditions of participation for hospitals less prescriptive, allowing hospital medical staff and administrations greater flexibility in the provision of inpatient medical care. Statutory requirements are still included, but the proposed changes ". . . are intended to simplify and clarify requirements, to focus on patient care, to emphasize outcome rather than the means used to achieve those ends, to promote cost containment while maintaining quality care, and to achieve more effective compliance with Federal requirements" (315). Beneficiary and labor groups have protested the new regulations, and the Secretary of Health and Human Services has delayed publication of the final rules by returning them to the Health Care Financing Administration (HCFA) (452).

Many of the existing conditions of participation for providers specify educational and experience requirements for personnel, similar to JCAH standards. Stringent personnel requirements can have several effects on the diffusion of medical devices. Requirements for highly trained (and therefore often expensive) personnel to perform certain tasks give providers such as clinical laboratories incentives to purchase capital equipment that reduces the number of personnel required to perform the task (provided the available personnel are already being used efficiently) (120,227). If such capital equipment is expensive, hospitals and facilities that provide services to inpatients must comply with section 1122 of the Social Security Act and State certificate-of-need (CON) regulatory programs required by the National Health Planning and Resources Development Act of 1974 (Public Law 93-641). These Federal and State programs, discussed further below, were responses by policymakers to several problems: the duplication of facilities and services, which contributed to the high cost of health care; access to health care, especially as it pertained to the maldistribution of services; and the high cost of medical care

Box L.—Joint Commission on Accreditation of Hospitals (JCAH)

The Federal standards for hospitals that were adopted for the Medicare program in the Social Security Amendments of 1965 were based on the 1965 standards for quality promulgated by JCAH. Congress had recognized the need for a method of quality assurance for the medical care to be paid through Medicare and Medicaid, and the JCAH standards were available and acceptable to medical professionals and the public (107).

JCAH was an outgrowth of the hospital accreditation program initiated by the American College of Surgeons in 1918 to ensure that hospitals had the necessary equipment and supplies for good quality patient care. In 1951, the financial burden of standard setting and facility surveying proved too great for the American College of Surgeons. JCAH was founded that year by joining the American College of Surgeons, American College of Physicians, American Hospital Association, American Medical Association, and the Canadian Medical Association for the purpose of accrediting hospitals. The Canadian Medical Association withdrew in 1959, when it formed the Canadian Council on Hospital Accreditation. The American Dental Association joined JCAH as a corporate member in 1979.

Hospitals must be in substantial compliance with JCAH standards in order to be accredited for a period of 3 years. They must demonstrate through a survey process that they meet the applicable standards, either through the hospital's own facilities and staff or by sharing some outside services. Shared services may be contracted for with another accredited hospital or an agency that maintains the level of performance required by JCAH standards. Each hospital must agree to conduct an interim self-survey at the midpoint between its JCAH surveys.

The 1965 JCAH standards adopted by Medicare for its conditions of participation included the requirement of urinalysis and hemoglobin or hematocrit tests for all patients upon admission. This requirement contributed to the overuse of tests and the medical devices involved in performing them. In the early 1970s, this standard was eliminated, and in 1979, JCAH reinforced the principle of "no standing tests" in a communication to its hospitals (222).

In general, JCAH standards do not specify medical devices that must be available in hospitals for accreditation; rather, the medical staffs at the hospitals are left to decide about particular medical devices that will assist in the provision of quality care. In certain instances, such as the emergency service/department, patient safety requirements specify medical devices and their maintenance. For example, the 1983 *Accreditation Manual for Hospitals* specifies in Standard II for Functional Safety and Sanitation:

> Methods and frequency of testing, and verification of performance—specifications and use-specifications, for all electrical and electronic patient care equipment, based upon established safety requirements, performance criteria, and manufacturers' claims. Such testing and verification shall apply to both fixed and mobile equipment, with particular emphasis on life-support such as respirators, defibrillators, physiologic monitoring systems, infant incubators and warmers, as well as devices with a high hazard potential such as electrosurgical equipment . . .

Standard-setting is an ongoing process in JCAH, and input is sought from specialty organizations, other experts in applicable areas, and relevant government agencies (such as the Health Care Financing Administration, which oversees Medicare). JCAH develops standards in response to identified needs to measure quality of a service or a particular aspect of care. New or revised standards may be needed when there are ". . . innovations in techniques, advancements in knowledge, changes in governmental regulations, or the demand by consumers for accountability. . . ." (176). The use of experimental devices, unlike experimental drugs which are addressed by JCAH, is not covered by a specific standard (222).

The assumption underlying the voluntary JCAH standards is that a necessary but not sufficient condition for good quality medical care is the availability of certain facilities, including medical technologies and staff. JCAH strives for the following characteristics for its standards: 1) validity, meaning that the standards relate to quality of care; 2) encouragement of excellence within available resources; 3) achievability, meaning that the standards have been met by an existing hospital; and 4) measurability (176). The effect of JCAH standards on the quality of care delivered in hospitals is anecdotal. Quality has improved, but a direct causal relationship has not been established.

borne by Medicare and Medicaid. The interaction of various Federal and State regulations for independent clinical laboratories is described in box M.

The effects of Medicare conditions of participation on the adoption and use of medical devices are unclear. Initially, there was an impetus for the Federal Government to approve as many hospital beds as possible so that the Medicare guarantee of access to medical care for elderly people would be operational on the first day of the program's implementation (7,107). In some cases, hospitals that had not previously been accredited because of failure to meet "contemporary standards of technology, staffing, and medical practice" were certified by Medicare as "in substantial compliance" (107). The incentives for facilities to achieve full compliance were weak, because hospitals with conditional certification were paid on the same basis as those in full compliance.

Since Medicare conditions of participation for hospitals were based on JCAH accreditation standards, any evidence on effects of the voluntary JCAH standards would apply to these conditions as well. Unfortunately, there is little evidence that accreditation has had an impact on the quality of care in hospitals or on the adoption of new medical technologies (227). Whether or not the conditions of participation affect the adoption and use of specific medical devices is impossible to prove because of the general lack of specificity regarding medical devices in most of the conditions of participation (and in the JCAH standards). Data sources for comparisons also lack specificity regarding medical equipment.

Medicare's diagnosis related group (DRG) based prospective payment system for hospitals, which was mandated by the Social Security Amendments of 1983 (Public Law 98-21) and is currently being implemented (see ch. 3), changes the environment for Medicare-based regulatory programs. Medicare's DRG hospital payment system may enhance the importance of conditions of participation for quality of care. The same law that mandated DRG payment also added a new "condition of payment": In order to be paid for treating Medicare patients, hospitals must contract with PROs (see "Utilization and Quality Review Programs" section below).

Utilization and Quality Review Programs

Utilization review programs in hospitals have been a condition of participation for hospitals participating in Medicare since the program's inception in 1966. In the original Medicare legislation, hospitals were required to have periodic reviews of the medical necessity of admissions, extended stays, and professional services rendered (42 CFR 405.1035 (a)). The purpose of these reviews was to help contain costs and to ensure quality of care. Medical device use was to be evaluated in connection with the review of professional services.

Congress mandated the PSRO program in the Social Security Amendments of 1972 (Public Law 92-603) to carry out these utilization and quality review responsibilities. PSROs, which as noted above are currently being replaced by PROs, are areawide groupings of practicing physicians designated by DHHS to review services provided to Medicare and Medicaid beneficiaries. Their purpose has been to ensure that the services Medicare and Medicaid pay for are: 1) medically necessary, 2) of a quality that meets locally determined professional standards, and 3) provided at the most economical level consistent with quality of care. Thus, the two objectives of the PSRO program have been quality assurance and cost containment (345).

In theory, PSROs were to accomplish these goals by conducting three types of evaluations in inpatient hospital settings, long-term care facilities, and ambulatory care settings:

- utilization reviews (e.g., reviews of the length of stay and medical necessity of admissions);
- medical care evaluations or quality review studies (e.g., audits of patient records to monitor the appropriateness of tests, drugs, and procedures administered to patients); and
- profile analyses (e.g., reviews of hospital physicians' patterns of care to identify potential problems).

In practice, PSROs have tended to emphasize utilization reviews in inpatient settings, focusing on the identification of high hospital admission rates and lengths of stay. One of the reasons is that identifying high usage of hospital care has proved easier than identifying underuse of hos-

Box M.—Interaction of Regulations for Clinical Laboratories That Test Ambulatory Patients[1]

Three general types of clinical laboratories perform tests for ambulatory patients: hospital-based, independent, and physician office laboratories. Regulations for each type depend on the States in which the laboratories are located and the patients whom they serve. Standards and regulations have been set by voluntary associations, such as the College of American Pathologists and the Joint Commission on Accreditation of Hospitals (JCAH), and by Federal and State Government agencies.

At the Federal level, there are regulations under Medicare and under the Clinical Laboratory Improvement Act (CLIA). CLIA was administered by the Centers for Disease Control until 1979, but since then has been administered, along with Medicare, by the Health Care Financing Administration (HCFA).

Laboratories that can be paid for tests on Medicare (and, usually, Medicaid) patients must meet the standards specified in the Medicare conditions of participation for hospitals or conditions for coverage of services of independent laboratories. Hospital laboratories that have been accredited by JCAH or the American Osteopathic Association are deemed to be in compliance with the Medicare conditions of participation.

Laboratories that conduct interstate business must meet the requirements of CLIA or be accredited by an association or licensed by a State with more stringent rules. Currently, only interstate laboratories that meet New York State licensure and the highest accreditation of the College of American Pathologists are exempt from CLIA requirements. Physician office laboratories are generally exempt from Federal regulations unless they annually accept more than 100 specimens on referral from other physicians.

Federal performance standards fall into three categories. First and most costly are educational and experience requirements for laboratory personnel. Personnel requirements under Medicare and CLIA are stricter for interstate and independent laboratories than for intrastate hospital laboratories. (The two Federal programs are almost identical now that they are both administered by HCFA.) Second, all interstate licensed laboratories and all Medicare-certified laboratories must comply with quality control requirements. Third, Federal regulations require external validation of a laboratory's performance via participation in proficiency testing programs.

In addition to complying with the comprehensive, detailed Federal regulations, laboratories in most States must comply with State licensing regulations. Hospital laboratories in 39 States are licensed through hospital licensing or separate laboratory licensing programs. In nine other States, there are requirements for specific tests performed in the hospital laboratories. Independent laboratories in 26 States must meet licensing requirements; and in 15 other States, they must meet requirements for performance of specific tests.

Physician office laboratories are licensed in Nevada, New Jersey, and Pennsylvania, where they must comply with specific regulations. In California, physician office laboratories that perform tests for Medi-Cal patients are regulated. Other States regulate physician office laboratories, depending on one or more of the following factors: 1) if there is more than a specified number of physicians; 2) if the laboratory accepts specimens on referral; 3) if the testing is done by a non-physician; or 4) if certain specialized tests are performed. Some States require all physician office laboratories to participate in proficiency testing programs.

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[1] Based on a paper prepared for OTA by Foster (120).

pital care or specific medical technologies. Furthermore, from the standpoint of reducing Medicare costs, reducing overutilization of hospital admissions and lengths of stay is clearly important. Reducing overutilization of hospital care is likely to be more cost saving than reducing underutilization, although it could be argued that from the standpoint of quality assurance, it is also important to consider the latter.

PSRO utilization reviews in hospitals, although not focused on particular drugs, devices, or medical procedures, may nevertheless have indirectly affected the utilization of specific medical devices. Quite conceivably, changes in hospital admission rates and lengths of stay may have indirectly affected the use of diagnostic tests and other device-based procedures routinely used for hospital patients.

Like PSRO utilization reviews, most medical care evaluations and profile analyses have been conducted by PSROs in inpatient hospital settings. Unlike utilization reviews, however, some medical care evaluations have been directly focused on the appropriate use (including underutilization) of specific medical devices.

Thus far, evidence on the effectiveness of review programs has been mixed. Analysts considering benefits of review programs have examined both cost savings and contribution to quality assurance. Evidence is inconclusive that utilization review programs have achieved net cost savings when reductions in length of stay and admissions are considered along with the costs of the review program (50,57,325,326,334,395,397,409, 411). Evidence that review programs have improved quality of care is limited but suggestive (57,395).

No specific evidence of the effects of PSRO or hospital review programs on the adoption and use of medical devices has been reported, although a study of one hospital showed that length of stay and average charges per patient (probably related to medical device use) generally decreased following institution of PSRO review. The decrease, however, did not result in savings to Medicare and Medicaid because of an increase in hospital admission rates also attributed to PSRO review (455).

As noted earlier, the Social Security Amendments of 1983 added as a new "condition of payment" for hospitals treating Medicare patients the requirement that hospitals contract with PROs. PROs have responsibility for monitoring ancillary service use and hospital discharges that result in quick readmissions, because Congress recognized the financial incentives under DRG prospective payment to use as few ancillary services (including those involving medical devices) as possible, to discharge Medicare patients as quickly as possible, and to admit as many cases as possible.

PROs, the replacements for the PSROs, are contract organizations that must affirm their utilization review and quality assurance objectives, as well as define their specific plans on how to attain these objectives, in their contracts with HCFA. Medical devices will be subject to evaluation under the PRO function to review the completeness, adequacy, and quality of care to hospital inpatients. A specific requirement in the scope of work for PROs is to monitor cardiac pacemaker implantations and reimplantations for unnecessary procedures (407).

Section 1122 Capital Expenditure Review

Section 1122 of the Social Security Act and State CON laws required by the National Health Planning and Resources Development Act (see "Federal Health Planning Regulations" and "State Certificate-of-Need Laws" sections below) potentially could have the most direct effect on medical devices of any of the provider regulations discussed in this chapter. Congress mandated section 1122 capital expenditure review in the Social Security Amendments of 1972 (Public Law 92-603). The purpose of section 1122 review is to ensure that Federal funds for Medicare, Medicaid, and the Maternal and Child Health and Crippled Children's Services programs are not used to support unnecessary capital expenditures by health care facilities. Section 1122 of the Social Security Act authorized the Secretary of Health, Education, and Welfare (now Health and Human Services) to enter into contracts with States that were willing and able to do so. Under these contracts, a State or State health planning agency would review expensive capital expenditures, and the Secretary could withhold reimbursement for expenditures that were disapproved.

Under section 1122, capital expenditures by specified health facilities that exceed a certain threshold—initially $100,000, currently $600,000—are subject to review by a State or State planning agencies. Also subject to section 1122 review are changes in numbers of beds or substantial changes in the services offered in medical care facilities. As of 1983, only 15 States had contracts with DHHS to conduct section 1122 capital expenditure reviews.

Section 1122 currently applies to hospitals, psychiatric hospitals, tuberculosis hospitals, skilled nursing facilities, kidney disease treatment centers, intermediate care facilities, and ambulatory surgery centers. Medicare and Medicaid reimbursement to these facilities can be denied only for unapproved *capital expenditures* (i.e., expenses related to depreciation, interest on borrowed funds, or, in the case of proprietary facilities, return on equity for capital equipment or construction). Reimbursement for operating expenses associated with unapproved capital equipment or construction is not affected.

Because of the high threshold for section 1122 review and the State-based decisionmaking process provided for in the law, the effect of section 1122 provider regulation on medical devices is probably similar to that of the State CON programs required by the National Health Planning and Resources Development Act of 1974 (see section on "State Certificate-of-Need Laws" below). Only a few devices—e.g., CT scanning and nuclear magnetic resonance (NMR) equipment—exceed the threshold for section 1122 review. Thus, most purchases of medical devices by the facilities to which section 1122 applies can be made without section 1122 review.

Federal Health Planning Regulations

Bringing together several strands of previous legislation, the National Health Planning and Resources Development Act of 1974 (Public Law 93-641) outlined national health priorities and replaced the existing network of voluntary agencies with a system of about 200 local health systems agencies and State health planning and development agencies. The purpose of this act and related health planning legislation was to centralize decisionmaking at the State level in order to rationalize resource allocation and control escalating rates of cost increases.

The 1974 law called for the provision of greater authority to State and local planning agencies over hospital investments. The law required State health planning agencies to review CON and section 1122 applications from medical facilities regarding capital investments. State planning agencies have the responsibility of determining the numbers and types of facilities and services needed by their populations. State Health Plans to accomplish the equitable distribution of these health care services are required by the Federal law. Agencies try to alleviate the perceived maldistribution of health services and to contain rising costs through CON programs.

Amendments to the 1974 National Health Planning and Resources Development Act established a two-level review process for CON programs. A medical facility must submit a detailed application to the local health planning agency, which subsequently reviews it. State health planning agencies have the authority to grant a CON, but they must carefully consider the recommendation of the local agency.

Minimum criteria and standards for CON review by the States are set forth in the Federal planning law. The State agencies must consider the relationship of the proposed services to the State health plan and to the provider's long-range plan, the targeted population's need for the proposed services, alternative means of meeting the need, the availability of resources for the proposed service and alternative health uses of those resources, the relationship of the proposed service to the existing health care delivery system, and special needs of health maintenance organizations (HMOs), among other criteria.

Current Federal law requires hospitals, skilled and intermediate-care nursing facilities, kidney disease treatment centers, rehabilitation hospitals, and freestanding ambulatory surgical centers to submit applications for capital expenditures under State CON programs. States vary in their coverage of other facilities, but few cover physicians' offices (see section on "State Certificate-of-Need Laws" below). Some facilities are exempt from the Federal requirement for CON applications for capital equipment, among them Federal hospitals and clinics (e.g., Veterans Administration medical centers). Medical research institutions and HMOs are given special consideration. These entities must notify the State CON agency that they intend to purchase a piece of major medical equipment, for example, and the agency must approve the purchase if specific applicant criteria are met and if need is demonstrated (Public Law 96-79 and Public Law 96-538).

Required applications for CON are triggered under Federal law by types of expenditures and by amounts of such proposed purchases. Proposed expenditures must: 1) exceed the threshold, 2) substantially change the bed capacity of the facility, *or* 3) substantially change the services of the facility. The original CON thresholds were: 1) $150,000 for capital expenditures, 2) $75,000 for annual operating costs resulting from changing services, and 3) $150,000 for major medical equipment to be used to provide medical and other health services. The CON threshold levels that have been in effect since 1981 are: 1) $600,000 for capital expenditures, 2) $250,000 for annual operating costs resulting from changes in health services, and 3) $400,000 for major medical equipment to be used to provide medical and other health services.[1] For changes in health services, CON applications are required if there is *any* capital expenditure or if annual operating costs exceed the specified operating cost threshold (129). Medical device purchases are included in CON applications in those instances in which the devices are very expensive or in which facility services are changed.

Since 1979, Federal law (Public Law 96-79) has required purchases of major medical equipment that will be used for medical treatment of hospital inpatients to be covered by State CON laws, regardless of who makes the capital expenditure. Gifts and donations of medical devices that would come under CON laws if they had been bought by the facility are also subject to CON requirements.

Capital equipment initially purchased for research purposes usually must be approved for later clinical use through the CON requirement regarding new institutional services. There are no national data available regarding how much medical equipment has initially been purchased for research purposes and then transferred to clinical service. Thus, the effect of this aspect of the CON regulation on the medical devices industry is unknown.

What are the sanctions or incentives that enforce the Federal planning law's requirement that States have CON laws? First, States that do not have such laws risk losing their Federal planning money. But Federal planning funds have decreased over the past few years, and the program has weakened. Second, and probably more important, if States do not have conforming CON laws, they are supposed to lose Federal funds from several Public Health Service programs (particularly those under the Community Mental Health Centers Act, Comprehensive Alcohol and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, and the Drug Abuse Office and Treatment Act of 1972—see Public Law 96-79, sec. 123(d)(2)).

The threat of these sanctions persuaded all but one State (Louisiana) to pass CON laws by March 1983 (406), although as of March 1984, only 23 States had CON programs in compliance with the minimum Federal requirements (129). Because the sanctions are not being applied under the present national law, however, Minnesota, Idaho, and New Mexico have allowed their CON laws to expire. For several years, the costs and benefits of the Federal planning program have been questioned by Congress. This debate has resulted in funding the planning program through continuing resolutions that have specified that noncomplying States not be penalized.

The future of the Federal planning program is uncertain. Budget decreases and the expressed intention of the Reagan Administration to dismantle planning have further weakened the existing

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[1] States have been given authority to adjust these thresholds to reflect the change in the previous year in the Department of Commerce Composite Construction Cost Index. For States that do so, the thresholds would be $695,285 and $289,782. The $400,000 threshold for major medical equipment may not be adjusted. (See Public Law 97-35 or proposed rule changes in the Jan. 4, 1983, issue of the *Federal Register* (315).)

Photo credit: General Electric

Nuclear magnetic resonance (NMR) imaging equipment, shown here, is one of the few medical devices that is expensive enough to be regulated under State certificate-of-need (CON) laws.

program. The Administration, however, seems to be reconsidering its position (453). New CON thresholds have been proposed in Congress (see box N), and the Office of Management and Budget has indicated a willingness to accept thresholds of $5 million for capital expenditures, $1 million for changes in institutional health services, and $2 million for major medical equipment (453). Although the fiscal year 1985 Federal budget contains no funds for health planning, the Administration has indicated that new, reasonable legislation would be considered favorably (37).

Health planning has many critics, but an indepth examination of the pros and cons of health planning is beyond the scope of this report. Specific criticisms of the Federal health planning program focus on the difficulty of determining the need for various health facilities and services. Methods of calculating need involve the use of demographic and epidemiologic data and require decisions based on the pros and cons of having excess or insufficient facilities on a periodic or sporadic basis. State and local planning agencies often rely on hospitals and other facilities for their data, which may pose problems of reliability. In considering the need for new medical technologies, data may not be available. State planning agency staffs may not have information on safety, efficacy, and cost effectiveness of new or old medical devices. Furthermore, agency personnel have been criticized for their lack of ability to use the data appropriately (61,111).

The effect of the Federal health planning regulations on medical devices is most distinct in the CON impacts examined in the section on "State Certificate-of-Need Laws" below.

STATE REGULATION OF PROVIDERS

At the State level, providers of medical devices are regulated in part through State licensure laws for facilities and personnel. They are also regulated through State CON laws, which are required by the Health Planning and Resources Development Act of 1974 (Public Law 93-641) to conform to Federal criteria. Capital expenditure reviews required by section 1122 of the Social Security Act were discussed in the section on "Federal Regulation of Providers" above. Although like CON reviews, section 1122 reviews are State based, the sanctions on facilities for noncompliance with the section 1122 are the withholding of Federal funds under Medicaid, Medicare, and Maternal and Child Health and Crippled Children's Services programs. The sanctions on facilities for failure to comply with CON, by contrast, are determined by individual States.

State Licensure of Facilities and Personnel

States have the power and responsibility to determine which providers may treat patients. To ensure a minimum level of quality for providers, State laws require hospitals, nursing homes, and other health care facilities to meet specific standards in order to be licensed to operate. Facility

Box N.—Legislative Activity in Health Planning, 98th Congress, 1st Session (1983)

H.R. 843 (McDonald). Repeals title XV (National Health Planning and Development) and title XVI (Health Resources Development) of the Public Health Service Act. Introduced Jan. 25, 1983. Referred to House Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment.

H.R. 1358 (Shelby). Repeals title XV (National Health Planning and Development) and title XVI (Health Resources Development) of the Public Health Service Act. Provides that such repeals shall not affect outstanding loan obligations. Establishes 20-year Federal recovery rights on facilities receiving title XVI construction grants. Introduced Feb. 8, 1983. Referred to House Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment.

S. 963 (Hatch, by request). Health Amendments of 1983. Repeals title XV (National Health Planning and Development) and title XVI (Health Resources Development) of the Public Service Act. Introduced Mar. 24, 1983. Referred to Senate Committee on Labor and Human Resources.

H.R. 2935 (Shelby). Health Planning Block Grant Act of 1983. Replaces title XV (National Health Planning and Development) of the Public Health Service Act with State health planning block grants. Specifies certificate-of-need (CON) program requirements, including thresholds of $1 million for institutional health services and $5 million for capital expenditures and major medical equipment. Introduced May 9, 1983. Referred to House Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment.

H.R. 2934 (Waxman). Health Planning Amendments of 1983. Amends Public Health Service Act to revise the health planning program under title XV (National Health Planning and Development). Repeals the program effective Oct. 1, 1986. Raises CON thresholds to $1 million for capital expenditures, $500,000 for changes in health services, and $500,000 for major medical equipment. Introduced May 9, 1983. Referred to House Committee on Energy and Commerce. Referred to Subcommittee on Health and the Environment. Reported to House by House Committee on Energy and Commerce. Placed on Union Calendar for action by full House.

S. 1778 (Quayle). Repeals title XV (National Health Planning and Development) of the Public Health Service Act and replaces it with the Health Planning Block Grant Act of 1983. Gives States discretion regarding participation. Repeals this act as of Oct. 1, 1986. Introduced Aug. 4, 1983. Referred to Senate Committee on Labor and Human Resources.

H.R. 850 (Gephardt). National Health Care Reform Act of 1983. Among many health care reforms, repeals specified provisions of Public Health Service Act concerning health maintenance organizations, health planning, and health resources development. Introduced Jan. 25, 1983. Referred to House Committee on Energy and Commerce, House Committee on the Judiciary, House Committee on Post Office and Civil Service, and House Committee on Ways and Means. Referred to subcommittees of the listed committees.

standards often include staffing requirements for licensed personnel who have met a set of licensure qualifications, such as education and experience. Virtually all States have hospital licensure laws, but licensure laws with respect to other types of facilities vary. State licensure laws also vary according to types of personnel. The specific standards and qualifications required are decided by the individual States (227).

Some licensure laws are more detailed than others regarding medical devices or, more frequently, necessary staffing and staff qualifications. Licensure laws are similar to the Medicare conditions of participation in their focus on structural aspects of quality assurance, such as compliance with construction codes and public health laws. Licensure regulations tend to be weaker, more ambiguous, and not so well enforced in matters that are more clearly related to patient care (227).

There has been little research on the influence of State licensure laws on the adoption and use of new medical technologies (227). It is probable, however, that licensure programs have had mixed effects on medical devices, depending on the specificity of the individual laws and how a particular device is related to personnel needs. In clinical laboratories, for example, the strict personnel requirements for laboratory licensure make equipment that reduces the number and skill level of personnel quite attractive (120).

On the other hand, licensure requirements may slow the diffusion of equipment that requires licensed personnel for operation (227). In addition, stringent rules to employ highly trained personnel in laboratories raise barriers to entry of new facilities in the market because of the difficulty of finding and expense of employing the required personnel (120). Both facility and personnel licensure, then, can affect medical device diffusion.

Another characteristic of State licensure programs themselves that probably affects the medical devices industry is the use of professional surveyors to inspect facilities. The subjectivity of some of the judgments needed to decide about licensing a facility can sometimes be the basis for challenging negative outcomes. Also, if review teams have a particular professional orientation, they can encourage the adoption of the best available new equipment (227).

State Certificate-of-Need Laws

Several States had CON laws prior to the enactment of the National Health Planning and Resources Development Act of 1974. In 1964, New York became the first State to enact and implement a CON law. Twenty-seven States had CON laws by the time the National Health Planning Act was passed. These States were required by 1980 to make their laws conform to the same minimum Federal standards as State CON laws enacted after 1974 (Public Law 96-79).[2] However, State CON laws differ with respect to the types of facilities covered, the standards and criteria used for CON review, and the amounts of the expenditures for which CON applications must be submitted (406).

As noted in the "Federal Health Planning Regulations" section above, current Federal law requires hospitals and other specified medical facilities to submit applications for capital expenditures under State CON programs. Some States require other types of facilities (e.g., freestanding emergency care centers and home health agencies) to submit applications, as well. Nine States require CON applications for equipment purchases for physicians' offices (453).

The focus of review when CON laws were first implemented after 1974 was on construction projects (i.e., modernizing old buildings and erecting new ones) and bed capacity changes (61). One of the reasons was that control over the costs of such projects implied control over further duplication of facilities and excess bed capacity that was blamed for some of the increase in health care costs. Another reason for the focus on construction and bed capacity changes when CON laws were implemented was that there were few medical technologies at the time that cost more than $150,000 (the original CON threshold). Furthermore, hospitals and other purchasers of medical equipment were able to circumvent the requirement for CON applications for equipment purchases in excess of the threshold by dividing orders into smaller expenditures that would not trigger the review process (42). If new laboratories were built or old ones renovated, construction was usually necessary and put the project over the CON threshold. If equipment purchases (regardless of price) changed the health services offered, or if the new services (regardless of capital expenditures) resulted in operating costs over $75,000 (again, the original threshold), CON applications would be required (129).

As CON programs matured and as medical equipment changed, more medical devices came under review. Highly innovative machines that altered the practice of medicine, such as the CT scanner, were introduced in the 1970s (see box O). Machines such as CT scanners presented CON agencies with difficulties because of their high cost

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[2] Costs and benefits of the Federal health planning program have been debated in Congress for several years. This debate has led to budget cuts and to continuing resolutions that do not enforce penalties on noncomplying States.

Box O.—The Impact of Certificate of Need (CON) on Computed Tomography (CT) Scanners and Nuclear Magnetic Resonance (NMR) Imaging Devices

Many of the issues encountered in today's debate regarding the costs and benefits of NMR imaging devices were also problems encountered when CT scanning equipment was introduced in the 1970s. The CON laws were changed to balance some of the incentives for CT, but their effect on NMR remains speculative.

One of the difficulties in the CON process for CT scanners was the lack of data on safety and efficacy for different medical conditions when CON applications were received (348). Physicians were experimenting with new uses of the machines, and manufacturers were improving the images and reducing the X-ray dosage for their machines. Some hospitals obtained CT scanners for investigational purposes, and when CON applications were later submitted, these institutions already had the machines and experienced personnel on staff. Furthermore, some CT scanners were purchased for hospitals by physicians or groups of physicians, since only hospital purchases were covered by most CON laws. Mobile CT units were also purchased and were able to serve several hospitals (349).

In 1979, CON laws were amended to include major medical equipment purchases for inpatient hospital use regardless of purchaser (Public Law 96-79). This change affected the private purchases of CT scanners for hospitals and the mobile units. Private purchases for nonhospital locations of CT scanning devices were exempt from most States' CON programs. The CON laws may thus have contributed to the maldistribution of CT scanners that was perceived as late as 1980 (23). The maldistribution of scanners has implications for access to care and perhaps for quality of care for the poor segments of the population who most often go to the hospitals that were not able to obtain CT scanners.

The price of head scanners declined over time, and hospitals that had waited to purchase them could do so without submitting CON applications because prices fell below the threshold. A change in the Federal regulations regarding CON programs in 1979 brought the head scanners back into the planning fold by using the "change in service" requirement (349). Upgrading equipment from CT head scanners to body scanners also came under CON review.

NMR imaging devices have been compared to the CT scanning devices because both have been expensive innovations that could change the practice of medicine. Both became popular while still in experimental stages of development. Just as CT head scans were further advanced in development when CT began to affect CON processes, NMR head images are further advanced than NMR body images. CON applications were submitted before there were adequate data from which to evaluate CT scanning equipment (349). Although NMR is still in a research stage, 33 CON applications had already been filed for NMR by October 1983 (451).

The prices of most NMR devices would trigger CON even if the thresholds were raised to the proposed $1 million for major medical equipment (100). Prices on CT equipment have fluctuated, but whether or not prices will decrease for some or all NMR devices is unknown. NMR devices would also trigger CON for changes in service and if construction costs for building or renovating facilities to house NMR equipment exceed the proposed $5 million CON threshold. Physical facilities must be modified more for NMR than for CT equipment. Both raise operating costs, and NMR devices require special personnel. When CT scanners first became a CON issue, third-party payment for their use was questionable. That is the case again with NMR. Private investors are purchasing NMR imaging equipment and locating it at nonhospital sites for the use of ambulatory patients. Thus, although NMR device use is still in a research phase, there seems to be a considerable amount of action in the market (100).

and the paucity of data on safety and efficacy. Physicians were still experimenting with new uses of CT scanners and manufacturers were still refining their machines when CON agencies received applications from hospitals and other covered facilities. In some cases, physicians and physician groups purchased CT scanners for their hospitals, to circumvent the requirement for CON approval (which in 1979 was extended to cover any major medical equipment to be used for inpatient care without regard to the purchaser or to the location of the equipment) (349).

The interaction of CON thresholds and equipment purchase prices is a potential source of influence on the diffusion of new medical devices. Over time, CON thresholds have increased. The prices of medical equipment also change over time as refinements are made or as components instead of a composite machine are sold, for example. The prices of medical equipment may go either up or down.

If new major medical equipment is priced above the CON threshold, delaying its purchase may save a facility money (unless the facility's resulting loss in potential operating revenues is substantial): if the price drops below the CON threshold, the facility may save not only the amount by which the price drops but also the administrative costs of the CON application. In the case of equipment that substantially changes the services provided by the facility, however, CON review would be necessary even if the price were to drop. In addition, facilities are prohibited from dividing projects into parts to avoid CON applications—each project must be a separate project (141).

Under the Federal requirements, State CON programs are to "provide for procedures and penalties to enforce the requirements of the program" (42 U.S.C. 300 m-2). Hospitals and other covered facilities must submit their CON applications to the State or local planning agency and abide by the approvals or denials or suffer the consequences. Sanctions against providers vary among the States but may include any or all of the following: denial or revocation of operating licenses, fines, civil or criminal penalties, and court injunctions (42 CFR 123.408 (b)).

Studies of the effectiveness of CON programs have shown that some States have used them successfully and others have not (133,436). Capital expenditures and health care costs have continued to increase despite CON laws, although both results may vary by State (436). Several researchers have studied the effects of CON on capital expansion; some have found evidence supporting capital limitation by CON and some have found evidence against it (436).

Studies of the effect of CON on cost control have produced no findings to support its ability to control health costs (436). Access to care for some patients has been improved, but there still seem to be excess bed capacity and duplication of services and facilities in some areas and shortages in others, all of which were to have been eliminated through CON (61).

There have been many studies of the impact of CON programs on capital expenditures (436). One of the early studies by Salkever and Bice showed that in States with CON laws, the number of beds decreased, but total hospital investment and assets per bed (which relate to medical devices) increased from 1968 to 1972 (270).

Hellinger, testing the hypothesis that the amount of hospital investment in States with CON laws would be less than it would have been without the CON programs (148), concluded that CON legislation had not significantly decreased capital expenditures. He then speculated that there would be a lagged effect because hospitals had anticipated the passage of the CON laws and spent higher than usual sums in the period before their implementation.

Warner has pointed out that because they do not specifically consider operating costs associated with capital purchases, CON programs do not evaluate whether equipment will ultimately save costs or increase costs (450). Operating costs of capital expenditures continue to be a source of health care cost increases (64).

Yet another study showed that in States with hospital rate-setting programs, increased capital expenditures may not lead to higher operating costs (96). Specific devices may be affected differently in different States. Russell found that the diffusion of cobalt therapy was not discouraged by the CON law in New York, but CON laws in other States have discouraged the technology's adoption of cobalt therapy (266).

A July 1982 study by the Wisconsin Hospital Association used data from the Wisconsin Hospital Association CON Data Base, its 1982 CON Survey, and State and local CON agencies' grant applications for 1978-81 to analyze the cost effectiveness of Wisconsin's CON program (462). The association found, using particular assumptions, that CON costs far outweighed the benefits. The investigators concluded that Wisconsin's CON program was not cost effective, did not suppress applications for capital expenditures (i.e., did not have a sentinel effect), had had its decisions reversed through administrative appeals, and had been unfocused and inconsistent in the substance of its reviews and in its determinations.

Looking at application and approval and denial data gives the impression that CON programs are accomplishing some of their goals. From 1979 to 1981, States reviewed more than 20,000 CON applications, which totaled more than $31 billion. Almost 10 percent of the applications were denied, saving an estimated 15 percent of the proposed expenditures (406).

These aggregate figures hide the facts that CON may have deterred an unknown number of applications and purchases and that the quality of the rejected applications is unknown. Some consultants specialize in CON applications (148), and manufacturers may send staff to assist hospitals in their CON applications (208). Small hospitals with less sophisticated technology are probably at a disadvantage in attracting or being able to pay for such help, and this may exacerbate the maldistribution of high-technology devices. Also among the unknowns are whether the distribution of services is being made equitably among the population and whether approved projects were needed more than those denied.

The costs of the CON programs themselves are substantial. In 1982, total Federal and State costs of administering CON programs were $16.9 million (406). Additional costs were probably offset by the CON application fees charged by half the States. Application fees and the other costs borne by the applicant facilities may discourage some applications. Whether the applications discouraged are frivolous or important for the health of the affected population is unknown. It is likely that examples could be found at either extreme.

Weighing the costs of the CON programs against their benefits is difficult because of the existence and interactions of Federal, State, and local regulatory programs and of complex goals. Competing goals, such as the elimination of excess beds and the assurance of access to health care, not only present CON programs with problems while they are evaluating applications, but also exacerbate the problem of identifying and measuring the benefits of regulation and planning.

CON programs would lose some of their control over capital expenditures if the thresholds were raised to the levels proposed by the Office of Management and Budget (i.e., $5 million for capital expenditures, $1 million for changes in services, and $2 million for major medical equipment). Clearly, fewer projects would require CON applications. Even some new facilities would be below the threshold unless they were specifically covered by CON laws. New freestanding emergency care centers, for example, have averaged $634,000 in building, land, and capital equipment costs (292). Capital expenditures that change institutional services and increase operating costs by $1 million annually would still require a CON, but their numbers would probably be small. High thresholds and the resultant low number of CON applications would save administrative costs for Federal and State governments and for the facilities.

If the Federal health planning program expires, the State CON laws will be voluntary (as far as the States are concerned). In 1984, the Office of Health Planning of DHHS has estimated that 37 of the States that have CON laws would keep them without the Federal requirement (129). A dozen States have "sunset" clauses that allow the CON laws to expire on specific dates; some others have sunset provisions tied to the anticipated demise of the Federal health planning program. Again, some States have CON laws that are more stringent and some have more lenient regulations than the Federal CON requirements.

The financial incentives for hospitals under Medicare's DRG hospital payment system currently being implemented (see ch. 3) change the roles of the CON laws and the planning program in general. Some of the effects will depend on how capital costs will be handled under the DRG system.[3] With DRG payment for inpatient operating costs (capital, outpatient, and direct teaching expenses remain "passthroughs"), hospitals have financial incentives to purchase technologies that lower their operating costs per case; and if they are expensive, these technologies may come under CON scrutiny. An anticipated response to the DRG hospital payment system is the movement of technologies from tertiary to primary care sites. This movement may be retarded in States where facilities other than hospitals are included under CON. The effect of such movement on costs will depend on whether the primary sites were replacing or supplementing hospital care and on the extent of total use that results.

DISCUSSION AND POLICY OPTIONS

Regulation of the providers of medical devices has been undertaken to control medical care costs, increase access to medical care (including devices), and control quality of care. Available evidence on the success that Federal and State regulation of providers has had in meeting these objectives is inconclusive. Health care costs continue to rise at a higher rate than the overall Consumer Price Index. Access to care is still a problem for some poor patients or patients in particular locations. Quality of care is difficult to define and measure, and problems remain in assessing quality concerns.

Conditions of participation for providers of services to Medicare beneficiaries and the new Federal requirement that hospitals contract with PROs (utilization and quality control peer review organizations) in order to be paid by Medicare have quality as well as cost implications. Changes in conditions of participation proposed by DHHS in January 1983 would give hospitals more flexibility in the provision of inpatient care, and medical devices may be affected even less under the new conditions than they were under the original set of conditions. Efforts have been made in the PRO regulations issued by DHHS to address previous problems with the PSRO program concerning quality review by requiring that evaluations of PROs have both cost and quality components. Evaluations of PSRO programs focused on cost-containment goals without adequately measuring quality of care. Thus, for example, such evaluations emphasized the ability of PSRO utilization reviews to decrease length of stay and hospital admissions.

Section 1122 of the Social Security Act pertains to review of capital expenditures and the Medicare, Medicaid, and Maternal and Child Health programs. Few medical devices come under section 1122 review because of the high threshold ($600,000). However, those devices that do also trigger CON review. The penalty for facilities that disregard section 1122 reviews would be stronger if the Social Security Act required the withholding of Federal program payments for operating costs associated with unapproved capital investments.

The Federal Health Planning and Resources Development Act requirement that States impose CON regulations on hospitals and other facilities in theory should have formed the strongest regulatory mechanism concerning the adoption and use of medical devices. Although CON regulations have attempted to contain costs and improve access, the evidence of their effect on medical devices is inconclusive: it is unclear whether CON laws have influenced the adoption and use of medical devices.

The results obtained by State CON laws may reflect certain characteristics of these laws. First, the laws have high thresholds for capital expenditures resulting in the coverage of few devices under these laws, and the laws ignore future operating costs. Second, the focus on hospitals by almost all the CON laws—although other sites are covered by some States (including physician offices in nine States)—may have contributed to duplication of technologies within the system. Third, the lack of a limit on the amount a CON agency can approve lessens the potential impact of CON on total costs. Fourth, the CON process is a reactive process in the sense of being dependent on the submission of CON applications by medical facilities. And fifth, political interactions among consumer patients, providers, and CON agencies influence the decisionmaking process.

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[3] Capital costs are now paid on a cost-reimbursement basis but will probably be paid on a different basis by 1986, since Congress mandated studies of how to treat capital costs under the DRG hospital payment system (Public Law 98-21). Any new capital payment method can be expected to change the hospitals' incentives regarding capital expenditures.

One problem with concluding from the mixed evidence that CON regulations have been ineffective is that incentives for health care facilities to buy whatever they wanted were embedded in cost-based reimbursement by third-party payers, and not all purchases were subject to CON requirements. Duplication of equipment among hospitals and other facilities in the same geographic area continues at least in part because facilities want to attract patients and physicians by providing up-to-date equipment. CON programs do not have the power to decide how much equipment is used or the ways in which it is used. Utilization and quality review programs can encourage the appropriate use of technologies, but decisions about use are basically left to physicians (and in some cases patients).

CON agencies have been hampered by unavailability of data on the health of the population and on the safety and efficacy of some new medical equipment, undeveloped techniques for determining need, insufficient budgets to hire appropriate planning agency staffs, and the political sensitivity of rationing health care. Furthermore, the regulatory agencies responsible for CON were advised by committees representing not only consumers but also the health care providers. CON decisions were thus compromises among parties with conflicting interests. All these difficulties have been exacerbated by constantly changing technology.

The following options present a range of possibilities regarding CON programs, from changing current regulations to eliminating them. The options concentrate on CON because of the relative availability of information on these programs and because of the direct impact on the medical devices industry.

Option 1: Expand the National Health Planning and Resources Development Act to require State CON laws to cover purchases of medical equipment regardless of setting.

This option would attempt to make the incentives of the Federal health planning act more neutral with respect to the location of certain medical devices by requiring that in addition to the hospitals, dialysis centers, and other facilities now covered by the act, physicians' offices, diagnostic centers, and other facilities now excluded by the legislation be required to submit CON applications before purchasing expensive medical equipment. Control over all sites of care would remove current incentives to place expensive devices in certain, mainly nonhospital, settings without regard to cost effectiveness. Maldistribution of medical equipment might still occur, though, because of the reactive nature of the CON process and the influence of other factors on placement.

Several States already have CON programs that cover major medical equipment purchases regardless of setting or ownership. Some States are encouraging hospitals to share equipment, such as new NMR devices in Nebraska (291). More sharing would be anticipated if all settings were covered, especially if a State had a limit on total CON approval. If such sharing became commonplace, different arrangements might be necessary to ensure quality (349). For example, facilities now carry liability insurance for their own physicians to use their medical devices; this type of insurance might have to be extended to other physicians using the devices.

Greater administrative costs to governments and providers from increasing the number of applications would result under this option. Although few medical devices are covered by CON thresholds, applications would increase since many of the settings that would be added by this option already purchase high-cost medical devices for which hospitals and other facilities are currently regulated. Regulatory staff would have to learn about health care delivery and needs for devices in these currently uncovered settings.

Option 2: Amend the National Health Planning and Resources Development Act to limit the level of capital expenditures that State CON agencies may approve in a year.

Because the funds for health care facilities and medical devices are limited, not all projects can or should be funded. Current CON approval or denial decisions are not necessarily made in light of information on different types of projects, and tradeoffs are not necessarily considered. A limit on the level of capital expenditures would necessitate comparisons among projects.

The Federal requirement that CON applications be batched so that similar projects are evaluated at the same time does not address the issue of tradeoffs among dissimilar projects. Hospitals that want to purchase new CT scanners, for example, may have to wait several months until the batch of applications is evaluated. Those applications are reviewed without regard to applications for other types of equipment or for buildings.

The Commission on Capital Policy of the American Health Planning Association recently recommended that future cost-based reimbursement for capital be limited by each State, subject to a Federal standard (5). The commission urged the adoption of limits that reflect the relative need of each State for modernization of facilities and for new services and facilities. It further suggested that capital payments within those limits be allocated by means of a planning and capital expenditure review process, presumably similar to the existing system.

If Medicare's DRG prospective payment system for hospital operating costs were extended to other payers, a State limit on total CON approval would become less useful. The reason is that hospital acquisitions would be constrained by the financial pressures to limit operating costs. A limit on the level of expenditures a CON agency could approve would also be less necessary if capital expenditures were included in DRG payments.

A major obstacle to the implementation of this option is the limit itself. Congress or the Administration might be the decisionmaking body for choosing the limit, but *how* would the limit be chosen? Techniques for determining a community's need for specific medical devices are still controversial. Determination of the need for the total capital expenditure in health care is clearly problematical. How much is the Nation or each State willing to pay overall for health care? How could that amount be apportioned between capital and operating costs, excluding preventive care for the moment? Would the limit be applied nationally or at the State level or locally? How should the budgeted limit be apportioned among the geographic regions or among the health care delivery sites?

The ultimate problem would be the selection of individual projects for funding in light of the lack of a generally valid decisionmaking method and the lack of theoretical or empirical predictions that the results of such a limit would be efficient or equitable.

Option 3: Amend the National Health Planning and Resources Development Act to eliminate the Federal CON requirement.

State CON programs have not been uniformly successful in controlling the costs and quality of, or improving access to, health care delivery. Health care costs are rising at a great rate, and some rural areas and urban public hospitals do not have the minimal requirements for some services that are outlined in the "National Guidelines for Health Planning" under the Federal health planning program. This option would eliminate the Federal requirement that States have CON laws, but would permit those States that wanted to continue their programs to do so.

Implementation of this option would eliminate the State and Federal Governments' administrative costs for the Federal program. It would also relieve hospitals—and in some States, other facilities—of the costs of application fees, personnel, and delays involved in the CON process.

The method of treatment of capital expenditures by the Medicare payment system will affect the need for regulations, especially if the DRG-based prospective payment system expands to other payers. In the past, Medicare has reimbursed hospitals for capital equipment on the basis of costs (see ch. 3). Medicare's DRG prospective payment system provides incentives for hospitals to reduce operating costs. If cost reimbursement for capital continues under Medicare's DRG payment system, hospitals will face incentives to purchase medical devices that will reduce operating costs. If payment for capital costs is more restricted, the incentive to purchase such devices will be weakened (but not eliminated).

No matter how capital costs are treated, socially desirable medical devices that raise operating costs may not be financially desirable to hospitals. CON programs could play a role in the proper diffusion of socially desirable but very expensive technologies if they could encourage particular facilities to purchase such technologies by offering special treatment on other applications, for example. At present, this kind of negotiating role would require changes in some CON laws.

Medicare's DRG-based prospective payment system itself may change the need for CON programs or for the national planning effort, especially regarding distribution of services. If the incentives of DRG payment work as anticipated, hospitals will specialize in treating patients in those DRGs in which they are efficient. Such specialization will follow a hospital's efforts to work with its medical staff to be cost conscious and to reduce the use of very expensive services. Some hospitals will continue to try to attract physicians and patients through purchases of the latest medical devices, but others will cut back some services.

Specialization among hospitals is likely to result from the dropping of services that do not pay for themselves through DRG payments. For example, a hospital that finds that its costs for staff, facilities, and equipment for coronary care are lower than the relevant DRG payment rates may specialize in coronary care. The same hospital may drop its pediatrics services if its costs are higher than the relevant DRG rates. Specialization could decrease duplication of medical devices and possibly eliminate excess capacity and lower excess use. CON programs may become unnecessary in light of these strong cost-containment incentives for hospitals, although the problem of duplication of services among nonhospital settings not covered by CON could be worsened.

If specialization decisions were made on a purely cost basis, however, it is clear that not all services or medical devices would be available to all segments of the population: areas of low population density or low income would suffer. The current planning process has not solved the problem of inequitable distribution of facilities and services. Some communities and population groups are still underserved, while certain areas have too many hospital beds. In addition, health planning has not thus far ameliorated the problem of public hospitals, which treat a disproportionate number of poor and elderly patients and which do not have the funds to renovate or to purchase necessary equipment.

7.

Veterans Administration Policies Regarding Medical Devices

War loves to play upon the young.

—*Sophocles*

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7.

Veterans Administration Policies Regarding Medical Devices

INTRODUCTION

The Veterans Administration (VA) has a prominent role in the medical devices industry from both the producer and purchaser sides of the market. Since the late 1940s, the VA has been an important source of research and development (R&D) funds, notably for rehabilitative technologies. In fiscal year 1983, the VA's total R&D budget was almost $160 million, of which over $10 million was specifically earmarked for rehabilitative R&D. Actively serving about 3 million out of 30 million veterans eligible for free health care and rehabilitative services with an annual budget of more than $8 billion, this agency is a significant power in the marketplace.

The VA presents a unique example of a health care system that includes the continuum of patients, needs, facilities, money, and personnel and the mandate to develop, deliver, evaluate, and support a full range of devices and services. Because of its size, the agency clearly has potential for influencing the medical devices industry. Yet although the VA health care system is completely funded by the Federal Government and centrally administered, decisions regarding the purchase and use of medical devices are primarily made at the clinical and VA medical center levels. Overall, the impact of the VA on the medical devices industry reflects this combination of targeted programs and policies and decentralized activities. The relationships among the parts of the VA discussed in this chapter are depicted in figure 4.

Throughout this chapter, medical devices are grouped and referred to in three classes:

- rehabilitative devices, such as prosthetics and sensory aids for disabled people;
- equipment, such as radiological and laboratory equipment; and
- supplies, such as bandages and other disposables.

The discussion begins with an overview of the VA health care system and then describes the VA's programs, activities, and policies with regard to the R&D, testing and evaluation, procurement and supply, and, finally, adoption and use of medical devices.

OVERVIEW OF THE VA HEALTH CARE SYSTEM[1]

The VA's health care system is the largest health care delivery organization in the Nation.[2] The vast majority of services are delivered to veterans in VA-owned facilities. Most acute care services are provided in 172 VA medical centers that are, for the most part, affiliated with medical schools. Begun after World War II, the affiliation program is generally credited with enhancing the quality of care at the VA hospitals. These hospitals operated over 82,000 beds in fiscal year 1981 and treated about 1.25 million patients.

The VA provides both institutional and noninstitutional long-term care services. Ninety-eight nursing homes associated with the VA medical centers provide highly skilled extended care after hospitalization. The VA plans to increase the number of nursing home beds from the 8,700 beds that were operated in 1981 to over 13,000 by 1987 to serve the rapidly expanding aged veteran population. Other institutional long-term care services are provided by the VA in community nursing homes, where services are purchased on a per diem basis, and at State veterans' homes, where the VA subsidizes care through grant programs.

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[1] Unless otherwise noted, this section is adapted from a discussion in U.S. Congress, Congressional Budget Office, *Veterans Administration Health Care: Planning for 1990*, Washington, DC, February 1983 (327).

[2] The Hospital Corp. of America, a private, "for-profit" hospital chain, includes more facilities, but has revenues only about half the size of the VA's health care delivery budget (130).

The VA also operates 15 domiciliaries, usually on the VA medical centers' campuses, where service-disabled or permanently disabled veterans can live and receive necessary minimal health care. Noninstitutional care provided includes day-care programs for the elderly and various home-care programs.

The outpatient programs operated by the VA represent an alternative to hospitalization for many veterans. In 1981, more than 15.8 million outpatient medical visits were made to VA staff, and 2.1 million visits were made to private physicians and funded on a fee-for-service basis by the VA. Clinic services are varied. In addition to diagnostic, treatment, and rehabilitative clinics, the VA operates mental hygiene clinics and day treatment centers for psychiatric patients and provides dental care services for long-term care patients.

In all, the VA employs the full-time equivalent of approximately 194,000 physicians, dentists, nurses, and administrative and support personnel. The VA's Department of Medicine and Surgery, headed by the Chief Medical Director, administers the entire health care system with an annual budget in 1983 of just over $8 billion. The Department of Medicine and Surgery is administered from the VA's Central Office in Washington, DC. Specific areas of patient care and program function (e.g., rehabilitation medicine, surgery, radiology, and medical research) are the responsibility of VA organizational units called services. As shown in figure 4, these units are under the guidance of service directors in the VA's Central Office.

The VA's health care system operates under a limited and controlled budget with plans projected for 1 and 5 years ahead. Funding is 100 percent Federal. Once Congress determines the overall appropriation, the budget is fixed for the following fiscal year. However, after the appropriation level is decided, the VA health care system is characterized by highly decentralized planning and financial management policies. Twenty-eight regional areas, called medical districts, control the allocations that are prospectively budgeted by the Central Office. Each medical district is typically composed of 4 to 10 VA medical centers.

The Veteran Patient Population

Currently, there are an estimated 30 million veterans eligible for health care services. About 40 percent of the eligible population are World War II veterans now in their 50s or 60s. By 1990, practically all of these 12 million World War II veterans will be over 65 years old, and the VA is concerned about the impact of this aging population on the health care delivery system.

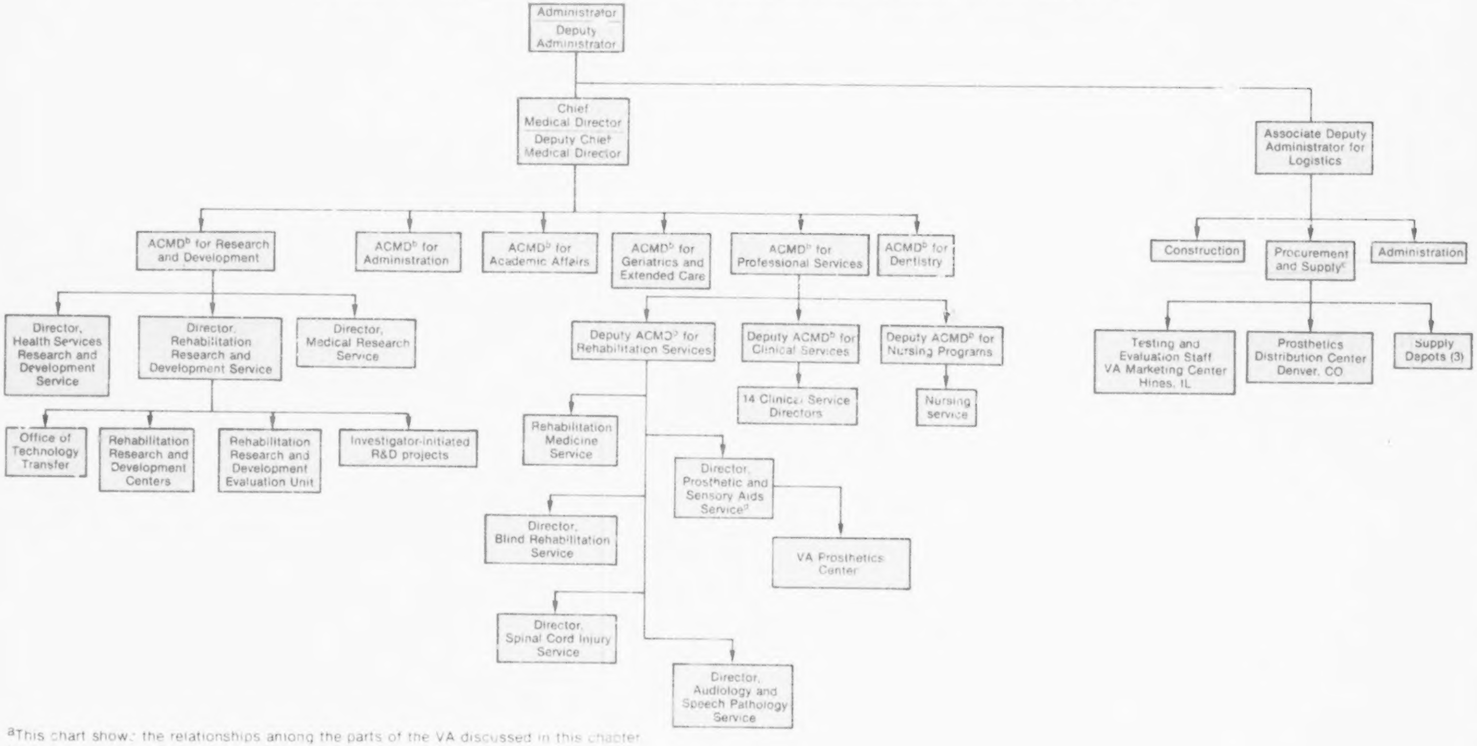
Only a small proportion of the eligible population actually uses the VA health care system, however. In 1981, about 3 million veterans, or 10 percent of those eligible, used VA services. Most veterans use community services for their health care, presumably because they have adequate public or private health insurance or they prefer the proximity of non-VA facilities. It is estimated that only about 2 million of the World War II veterans will apply for VA health care benefits when they are over 65 years of age.

Any veteran with a service-connected disability is eligible for health care services. Veterans with service-connected disabilities represented about 34 percent of the applicants who sought medical care from the VA in fiscal year 1982. The remainder of the VA patients were veterans aged 65 or older (about one-fourth of patients discharged from VA hospitals in 1981), veterans who were unable to pay for their medical care, former prisoners of war, and veterans who were exposed to Agent Orange in Vietnam. Other veterans are eligible on a space-available basis.

Veterans' Service Organizations

A number of veterans' service organizations play a significant role in the overall delivery of health care by the VA (106). In terms of size of membership, the major organizations are The American Legion, the Veterans of Foreign Wars, and the Disabled American Veterans. At the national level, these groups lobby for services and

Figure 4.—Organization Chart of the Veterans Administration (VA),[a] May 1984


Administrator
Deputy Administrator
Chief Medical Director
Deputy Chief Medical Director
Associate Deputy Administrator for Logistics
ACMD^b for Research and Development
ACMD^b for Administration
ACMD^b for Academic Affairs
ACMD^b for Geriatrics and Extended Care
ACMD^b for Professional Services
ACMD^b for Dentistry
Construction
Procurement and Supply^c
Administration
Director, Health Services Research and Development Service
Director, Rehabilitation Research and Development Service
Director, Medical Research Service
Deputy ACMD^b for Rehabilitation Services
Deputy ACMD^b for Clinical Services
Deputy ACMD^b for Nursing Programs
Testing and Evaluation Staff VA Marketing Center Hines, IL
Prosthetics Distribution Center Denver, CO
Supply Depots (3)
14 Clinical Service Directors
Nursing service
Office of Technology Transfer
Rehabilitation Research and Development Centers
Rehabilitation Research and Development Evaluation Unit
Investigator-initiated R&D projects
Rehabilitation Medicine Service
Director, Prosthetic and Sensory Aids Service^d
Director, Blind Rehabilitation Service
VA Prosthetics Center
Director, Spinal Cord Injury Service
Director, Audiology and Speech Pathology Service

[a] This chart shows the relationships among the parts of the VA discussed in this chapter.

[b] ACMD = Assistant Chief Medical Director.

[c] VA supply services are located in individual VA medical centers.

[d] The Prosthetic Technology Evaluation Committee advises the Prosthetics and Sensory Aids Service.

SOURCE: Office of Technology Assessment.

attempt to influence legislative decisionmaking. At the local level, they are involved in a variety of activities including substantial support for community programs. Because of their high visibility in the community, local chapters of these organizations can have an important influence on VA hospital activities. Hospital administrators are sensitive to their inquiries and complaints and usually try to consult these organizations when major planning decisions are under consideration.

RESEARCH AND DEVELOPMENT

The goals and priorities of the VA's R&D program are diverse, with broad mandates to address the very complex and difficult problems of veterans. The official role of the Federal Government in the R&D of medical devices, especially prosthetic and disability-related research, dates back to the 1930s and 1940s. Since 1947, the VA has spent over $25 million on prosthetic device research alone (225).

Research indicates that the Federal Government can be particularly effective in sponsoring R&D if the Government is itself the buyer of the resulting technologies (228). The VA spent well over $1 billion on all supplies and equipment for its various medical facilities in 1983. Especially in the area of rehabilitative devices, not only is the VA the major buyer in the country, but its R&D efforts are very important because of the small and fragmented nature of the market for many rehabilitative technologies.

Table 38 shows the VA budget for R&D activities, as divided among the VA's three major R&D services: the Medical Research, the Rehabilitation Research and Development, and the Health Services Research and Development Services. Although funds committed to these R&D services by the VA in current dollars have increased over the past few years, the budgets of these services have been stable or declining if inflation is taken into account. Furthermore, total R&D as a proportion of medical care expenditures by the VA has been steadily declining for a decade. In fiscal year 1970, R&D budgets accounted for 3.4 percent of the outlay for the medical care program, compared with only 2 percent in fiscal year 1982 (433).

Veterans' service organizations have expressed concern about effective cutbacks in R&D budgets, especially in the areas of prosthetics research and research on sensory aids for blind and hearing-impaired veterans. The organizations argue that these research areas have received decidedly less funding than they merit (344).

The bulk of R&D funds goes to the Medical Research Service, which provides opportunities for clinician and nonclinician scientists to study health problems in the veteran population. The emphasis of the medical research is on clinical research, most of which is initiated by physician investigators who carry out their research part-time and spend the majority of their time treating veteran patients. Current studies involve cardiovascular, respiratory, and renal devices. A number of research projects are also conducted cooperatively, with clinical trials at multiple sites within the VA medical care system. The largest number of cooperative studies have tested drug therapies, fol-

Table 38.—Veterans Administration (VA) R&D Budget Overview, Fiscal Years 1977-83 (thousands of dollars)

	Fiscal year						
	1977	1978	1979	1980	1981	1982	1983
Medical Research Service	$101,567	$108,153	$118,016	$122,745	$129,943	$130,842	$141,052
Staffing	4,220	4,367	4,217	4,171	4,171	3,845	4,015
Rehabilitation R&D Service	4,419	5,502	7,191	8,085	8,784	7,185	10,001
Staffing	69	90	112	143	–143	128	250
Health Services R&D Service	3,604	2,996	3,004	3,153	3,083	2,828	3,786
Staffing	45	90	105	104	104	93	120
Total	$113,924	$121,198	$132,645	$138,401	$145,942	$144,921	$159,224

SOURCE: U.S. Veterans Administration, 1983.

lowed by surgical procedures, such as coronary artery bypass surgery (342).

The Health Services Research and Development Service, which was organized in 1976, develops and supports programs designed to improve clinical and administrative decisionmaking in the VA medical care system. Its only research priority area that concerns medical devices is the assessment of the cost effectiveness of patient care technologies. The third VA service, the Rehabilitation R&D Service, is substantially involved with research and medical devices, as described in the following section.

Rehabilitation Research and Development Service

The Rehabilitation R&D Service is the result of an increased focus, both at the VA and at the national level, on rehabilitation research and engineering needs. In 1973, this program was separated from other R&D efforts at the VA and given a mandate to improve the quality of life and to facilitate greater independence for physically disabled veterans.

The Rehabilitation R&D Service undertakes research, development, and evaluation of new rehabilitative devices and techniques. The main goal of the program, which is primarily oriented to sophisticated equipment, is to develop "usable" devices that assist individuals. All activities are coordinated with the National Institute of Handicapped Research at the Department of Education. The Rehabilitation R&D Service is also concerned with technology transfer, including increasing the availability of new devices on the market (352).

The activities of the Rehabilitation R&D Service are concentrated in three areas—prosthetics, spinal cord injuries, and sensory aids, representing the most prevalent service-connected disabilities of veterans. Prosthetics research makes up about 40 percent of the Rehabilitation R&D Service budget; research relating to spinal cord injuries, with an emphasis on improving wheelchairs, makes up about 30 percent of the budget; and research on sensory aids, which include aids for visually and hearing-impaired people and for communication disorders, makes up the remaining 30 percent (426). Research priorities within these areas are identified through a combination of internal review and workshops and seminars, which include representatives from provider and research groups, manufacturers, and disabled veterans' organizations.

The Rehabilitation R&D Service supports both intramural and extramural R&D programs, although over the past few years, funding has shifted away from extramural projects and toward intramural projects such as VA-established centers and their university-affiliated programs. Two rehabilitation R&D centers, tied directly to the VA Rehabilitation R&D Service, have recently been established: one in the Palo Alto VA Medical Center in California and the other in the Hines VA Medical Center in Illinois outside of Chicago. Six more such centers are planned by 1986.

The rehabilitation R&D centers are affiliated with leading engineering schools in the same way that the VA medical centers are affiliated with medical schools. These affiliations bring faculty and students into clinical research settings to study the problems of disabled people and to investigate new procedures and devices to alleviate their problems. The rehabilitation R&D centers' primary goal is to apply advanced technology, such as microprocessors, to assist physically handicapped veterans.

In an approach similar to the rehabilitation R&D center concept, the Rehabilitation R&D Service is establishing university-affiliated research engineering programs to help support qualified engineering graduate students and faculty who undertake rehabilitation engineering projects. The thrust of the program is to interest engineering students in rehabilitation engineering and to create a flow of ideas and information between academia and the VA (69,125).

VA Prosthetics Center[3]

The VA Prosthetics Center is a VA R&D center in New York City that is within the Prosthetic and Sensory Aids Service (see fig. 4). The VA Prosthetics Center was established in 1956 to conduct R&D in rehabilitation engineering, to evaluate and test commercially available rehabilitative devices, to provide direct patient care for difficult prosthetic and orthotic cases, and to manufacture orthopedic footwear and prosthetic/orthotic devices.

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[3] Since its inception in 1956, the VA Prosthetics Center has also been known as the VA Rehabilitation Engineering Center (VAREC) and as the Prosthetic Evaluation Testing and Information Center (PETIC).

In its earlier years, the VA Prosthetics Center was the "flagship" of a successful VA intramural research program in prosthetics and orthotics. The majority of the prosthetic limbs and the fitting techniques used today, for example, were developed by the VA Prosthetics Center in the 1950s (431). However, a 1983 audit report by the VA's Office of Inspector General found management and operating problems at the VA Prosthetics Center, then known as the VA Rehabilitation Engineering Center (VAREC) (426). The report recommended changes in VAREC's organization, including discontinuation of the R&D program. The VA's Department of Medicine and Surgery accepted the Inspector General's recommendation, disbanded the VAREC Research and Development Service in fiscal year 1984, and changed the organization's name to the Prosthetic Evaluation Testing and Information Center (PETIC) (430).

The VA Prosthetics Center encouraged innovation in the past by demonstrating that new types of wheelchairs were technologically possible and safe, and, most importantly, that there was a substantial market for them—the VA (282). The Prosthetics Center's work with power wheelchairs in the early 1970s demonstrated that electric wheelchairs could be used safely at speeds greater than a slow walk and that they could be designed to be used on rough terrain. This situation encouraged wheelchair manufacturers to begin making chairs with those capabilities. Efforts centered around lightweight sports wheelchairs had a similar effect on manufacturers.

TESTING AND EVALUATION

Literally thousands of disability-related devices are being produced by the public, private, and nonprofit sectors. Although many are relatively simple and low-cost items, others are expensive and complex. Regardless of the devices' cost, use, or complexity, certain criteria need to be met before these products enter widespread use. Safety and effectiveness, including durability and recommended applications, are the essential criteria that need to be evaluated (412).

Currently, the responsibility for testing and evaluating medical devices is divided among several VA organizational units. *Prototype* rehabilitative devices that are still in the developmental stage are evaluated by the Rehabilitation R&D Service. Once medical devices are *commercially available*, the responsibility for evaluation is split between: 1) the Prosthetic and Sensory Aids Service, which evaluates rehabilitative devices; and 2) the Office of Procurement and Supply, which evaluates all nonrehabilitative devices, equipment, and systems purchased by the VA.

Prototype Rehabilitative Devices

Rehabilitative devices developed by the VA often do not complete the transition from research prototypes to commercially viable products. The VA's research funds have supported a number of expensive prototypes that have been neither put into general use for the veteran population nor discarded outright. Examples include a wheelchair with special electronic controls adapted for use in a vehicle, a four-bar linkage knee for use in above-knee prostheses, and a standing device for paraplegics (433).

Although there are several reasons for the failure of such prototypes to become viable products, one obstacle is the lack of unbiased evaluations of the prototypes that provide data on performance and clinical applications. The inadequacy of internal testing and evaluation for prototype rehabilitative devices has been generally recognized by the VA. Although some VA facilities, including the rehabilitation R&D centers, the VA Prosthetics Center, and individual VA medical centers, have been involved in testing new and emerging devices through various VA services, the Rehabilitation R&D budget has not provided adequate funds to purchase expensive prototypes for clinical evaluation (433). Moreover, the VA has had a general procurement policy of not purchasing equipment unless it is commercially available and in clinical use (344).

There have also been concerns about unnecessary duplication in rehabilitative device evaluation when the Rehabilitation R&D Service has conducted testing. For example, special recreational ski equipment for disabled people, which was developed and tested at the Palo Alto Rehabilitation R&D Center and then further tested at four independent centers, could not be purchased for veterans until the equipment had gone through an essentially duplicative testing process at the VA Prosthetics Center (19,196).

In response to these criticisms, the Rehabilitation R&D Service has recently established the Rehabilitation Research and Development Evaluation Unit, a coordinating group to conduct clinical evaluations of new devices, techniques, and concepts in rehabilitation and to promote commercialization of the prototype devices that are evaluated by the program. The new unit will be responsible for developing evaluation protocols and will generally oversee and coordinate the evaluation process. However, all the organizational units within the VA that have a stake in the devices' development and ultimate commercial success will share in funding the major evaluations (435).

Although it is premature to assess the Rehabilitation R&D Evaluation Unit at this time, the unit appears to have the potential of coordinating work so that evaluations are perceived as valid by organizational units of the VA that use the results and duplication of effort is avoided.

In an attempt to further structure its technology transfer efforts, the Rehabilitation R&D Service has recently entered into an interagency agreement with the U.S. Department of Commerce to identify and develop potential markets and financing for prototype devices that were funded and developed by projects of the Rehabilitation R&D Service. The goal of the interagency program is to develop a process that leads to the commercialization of VA devices and technology.

Commercially Available Rehabilitative Devices

Once rehabilitative devices are commercially available, the responsibility for their evaluation shifts from the Rehabilitation R&D Service to the VA's primary user service, the Prosthetic and Sensory Aids Service. Throughout the 1970s, the Prosthetic and Sensory Aids Service increasingly employed performance standards in its prosthetic and sensory aids program. These standards are developed with the participation of individuals and organizations both within and outside the VA. Manufacturers, professionals, VA supply specialists, and others review the standards, which provide product specifications to control devices' quality, safety, and performance.

After a performance standard for a rehabilitative device has been established, the VA Prosthetics Center tests the device for compliance with the standard and determines whether or not products meet the VA's requirements. As noted earlier, the VA Prosthetics Center has recently become the VA's organizational focus for evaluation of commercially available rehabilitative devices.

The testing protocols used by the VA Prosthetics Center range from simple validation assessments to complex clinical evaluations involving dozens of VA medical centers or clinics. At the least, rehabilitative devices are tested for safety, reliability, and the validity of manufacturers' claims.

Devices can undergo either special laboratory testing or "field testing" at VA medical centers. Field testing, although advantageous in that it assesses devices' "usefulness," has never been utilized extensively by the VA Prosthetics Center because of organizational difficulties. Until fiscal year 1984, no line authority existed from the VA Prosthetics Center staff or from the Prosthetic and Sensory Aids Service to the medical centers. The absence of line authority has typically resulted in loss of control over adherence to protocols and lack of reliable reporting of evaluation data (465).

The VA evaluation process for commercially available rehabilitative devices has increasingly been the target of complaints, particularly from veterans' groups. The Disabled American Veterans has characterized the evaluation system as being "fraught with inefficiencies and communication breakdowns" (439). There has also been criticism on several other fronts: that testing priorities are not adequately established; that long lags exist in the evaluation process; that the needs of veterans for devices should be better anticipated; that the devices should be evaluated for safety by the Food and Drug Administration instead of by the VA; and that the VA should test for efficacy and cost effectiveness.

The standard-setting process has also been a cause of concern for veterans' organizations and others. Critics claim that the VA specifications have often been written to the specifications of a particular manufacturer's product, putting other manufacturers at a distinct disadvantage in the VA market. If such specifications define the dimensions and materials to be used in devices, it is more difficult for emerging devices that are different in design or performance levels to enter the general marketplace (352).

Shepard and Karon, who studied the VA's effects on the wheelchair industry, concluded that the large population of users in the VA could afford an opportunity for the VA to expand its role in postmarketing surveillance of wheelchairs (252). Such surveillance could yield better data on the frequency of repairs and the advantages and disadvantages of particular models during actual use. VA standards in the past had apparently been tied to the design of a particular wheelchair (manufactured by Everest and Jennings) rather than based on performance. The need for performance-based standards in the future has been recognized, and the VA has taken steps to produce such standards. VA standards are important to the industry, as evidenced by responses to Shepard and Karon's telephone survey. One manufacturer stated that it hesitates to make anything that it cannot sell to the VA; other manufacturers stated that VA standards are considered when they make R&D decisions (282).

The VA exercises its greatest market power in the "depot" wheelchair, an inexpensive general-purpose manual wheelchair. On the one hand, the VA's large purchases of this model reduce its price to the VA. On the other hand, the VA tends to discourage ordering of chairs with more user features or better technology. If alternative models were also stocked, price advantages could still be obtained (although possibly not so good as the present ones) and more desirable features, such as lighter weight, could be offered to disabled veterans (281).

Over the past 2 to 3 years, the VA procurement process has replaced most standards and device specifications with more general purchase descriptions—commercial item descriptions (CIDs)—that are designed to accommodate the variety of privately developed and marketed devices (32). CIDs are simplified product descriptions that identify by functional or performance characteristics the available, acceptable commercial products for Government use.

Currently, the VA has standards for only four or five rehabilitative devices, though these standards are applied to a wide range of devices. For example, the standard for wheelchair lift systems covers 21 different models and 13 different manufacturers. The increased use of CIDs, however, has also been criticized. A 1982 study by the U.S. General Accounting Office concluded that the CIDs contained too little specific information, with the result that the VA was purchasing many medical items that were either unnecessary or of lower quality (332).

To address these concerns, the Prosthetic and Sensory Aids Service initiated the Prosthetic Technology Evaluation Committee in 1982. This committee has developed an evaluation and coordination process for rehabilitative devices that will soon be operational in the VA system.

The Prosthetic Technology Evaluation Committee's strengths lie in two areas. First, the committee will coordinate evaluation activities with all the concerned participants inside the VA system, as well as with other Federal agencies, independent testing labs, and veterans' organizations. Representatives from the VA's Prosthetic and Sensory Aids Service, Office of Procurement and Supply, Inspector General's Office, Rehabilitation R&D Service, Rehabilitation Medicine Service, and from the Paralyzed Veterans of America and the Disabled American Veterans are permanent members of the Prosthetic Technology Evaluation Committee. Second, the committee will classify devices into three product levels according to potential level of risk, innovation, and cost, and the classification will determine the types of evaluations that the devices will undergo.

The Prosthetic Technology Evaluation Committee has enlisted the support of important consumer groups such as the Paralyzed Veterans of America and The American Legion, and it appears to be taking the necessary steps toward a more coherent and well-focused program of evaluation (245,288). But the committee still has some problems to resolve—such as expanding the VA Prosthetics Center's field-testing activities, making evaluations more national in scope, and establishing the committee's authority over the evaluation activities of the VA medical centers.

Commercially Available Equipment and Supplies

At any given time, at least 250 nonrehabilitative devices, ranging from hospital-based equipment to supplies and disposables, are being reviewed by the VA's Office of Procurement and Supply as a prerequisite to procurement contracts. Its Testing and Evaluation Staff, which was established in 1976 and is part of a larger marketing center and supply depot in Hines, Illinois, has primary responsibility for this aspect of the VA's device-testing activities.

The Testing and Evaluation Staff, with fewer than a half-dozen professionals, also has responsibility for a market research and analysis program. The staff identifies specific medical devices for evaluations through requests by VA medical centers, manufacturers, and the VA Central Office, as well as through in-house initiatives. Factors such as volume and interest expressed by VA health care facilities are usually more important than the cost of the products (238).

Thus, evaluations of nonrehabilitative equipment and supplies are primarily carried out on standard stock items and smaller medical equipment. Very expensive equipment, such as computed tomography (CT) scanners, is not evaluated by the Testing and Evaluation Staff; the service directors in the VA's Central Office are responsible for approving or disapproving the acquisition of such "controlled items." These central purchase decisions are based on either test data generated by manufacturers, local medical equipment committees in individual medical centers, or, in a few instances, interdisciplinary advisory committees convened by the Central Office.

The Testing and Evaluation Staff's evaluations are usually internal "consumer research" efforts aimed at validating manufacturers' claims about their products. VA regulations prohibit explicit comparison of one product with another. Although some evaluations of classes of devices have been attempted—evaluations that begin to move toward analyses of relative efficacy or cost-effectiveness—staffing and budget constraints have restricted the number of these efforts (238).

Typically, tests on individual devices are carried out at VA medical centers around the country and take the form of user surveys. The results are synthesized into very short summaries and published quarterly by the VA Office of Procurement and Supply. The Testing and Evaluation Staff also manages a computerized information system with price and marketing data on medical devices.

The results of evaluations of nonrehabilitative equipment and supplies by the Testing and Evaluation Staff are well disseminated to users within the VA health care system. Although the Office of Procurement and Supply is sometimes reluctant to publish the test results because the particular needs of veterans may be different from the needs of the general population, such information is routinely requested by non-VA hospitals, nursing homes, and State and local governments. Manufacturers are not permitted to use the VA's evaluations in their own literature, but private publications such as *Consumer Reports, Hospital Purchasing Management,* and *Health Devices Alert* often reprint survey results (68,238,434).

The Testing and Evaluation Staff's evaluations are *advisory* in nature. Although not scientifically rigorous, these evaluations do provide an information base for purchasing by individual VA facilities. The Testing and Evaluation Staff's evaluations are, by all accounts, most often used by smaller, more rural VA facilities. The VA estimates that only about 20 percent of its medical centers strictly adhere to purchasing decisions based on the evaluations.

PROCUREMENT AND SUPPLY

The VA Office of Procurement and Supply is responsible for supplying the most extensive medical program in the Federal Government. In fiscal year 1982, the VA spent nearly $1.3 billion on supplies and equipment for its various medical facilities. Totaling nearly 6,800 employees, the procurement and supply effort includes staff at the VA Marketing Center (VAMKC), the VA's Central Office, three supply depots, the Prosthetic Distribution Center, and 172 individual medical centers. Procurement staff have the twin goals of purchasing devices at the lowest possible cost and assuring the delivery of quality supplies and equipment for veterans. Efforts are divided between central procurement activities and the local supply activities of the VA medical centers.

Central Procurement by the VA Marketing Center

VAMKC in Hines, Illinois, is the focus of the VA's national purchasing activity. That VAMKC has acted as the contract negotiator and administrator for the U.S. Public Health Service, the armed services, and other Government agencies as well as for the VA has greatly enhanced its market leverage. In July 1983, VAMKC's shared procurement program with the Department of Defense, for example, was awarding annual contracts of $295 million (428). Overall, VAMKC procurement accounts for a substantial, but not dominant, proportion of national demand for medical equipment and supplies. Bradburd found that VAMKC procurement accounted for 5 to 10 percent of the national sales volume in the markets for X-ray, nuclear diagnostic, hemodialysis, and patient monitoring equipment (344).

The market power of the VA allows it to obtain favorable prices on medical supplies through its centralized procurement channels (167). Volume purchases of medical supplies and equipment are managed and distributed through three VA supply depots located in Somerville, New Jersey; Hines, Illinois; and Bell, California. The Prosthetic Distribution Center in Denver, Colorado, serves the approximately 200,000 veterans with service-connected disabilities. In fiscal year 1982, VA medical centers obtained about $198 million in supplies (about 15 percent of their total procurement needs) from the central supply depots (428).

Several other centralized procurement programs provide individual medical centers with opportunities to obtain economically priced supplies and equipment without having to solicit and award contracts. Under the Federal Supply Schedules program, the Government contracts with commercial vendors for a wide range of supplies and services at preestablished prices. VAMKC manages Federal Supply Schedules' contracts for medical drugs, chemicals, supplies, and equipment, while the General Services Administration manages the contracts for most other items, such as furniture and office supplies (335). About 34 percent of total purchases by VA medical centers, or $434 million, were made through the Federal Supply Schedules program in fiscal year 1982 (428).

Decentralized contracts are similar to the Federal Supply Schedules program, in that medical centers order from VAMKC-administered contracts. Usually these contracts, which account for only about 3 percent of total purchases by medical centers, are for specialized medical equipment that is unavailable through either the supply depot or Federal Supply Schedules programs.

The impact of VAMKC's centralized procurement policies and procedures on product prices was studied by Bradburd specifically for this OTA report (42). The study examined VA procurement of nine categories of major medical equipment. Although the market was found to be highly concentrated, the volatility of market shares and the very rapid pace of technological change suggested that the market was also extremely competitive.

Bradburd's findings with regard to six VAMKC procedures or policies are presented below (42).

Brand Name Justification

When a VA hospital receives authorization to purchase a particular item of equipment, VAMKC forwards to the hospital a list of the suppliers on contract whose equipment meets the requirements of the purchase order, ranked by order of cost. The hospital is required to purchase from the least-cost supplier unless it can justify purchasing from a different source based on service availability or another acceptable consideration. This exception process is called a brand name justification. Because suppliers are anxious to maintain their share of the VAMKC market, the brand name justification requirement puts them under pressure not to price themselves out of the VAMKC market, and this concern almost certainly results in lower prices than would be obtained in the absence of this requirement.

Firm Fixed-Price Clause

Under the terms of a VAMKC contract, suppliers are not allowed to increase prices during the contract year. Furthermore, if they lower the price at any time during the year, the lower price holds for the balance of the contract year. The firm fixed-price clause may or may not result in lower procurement costs. During the course of the business year, there are times when suppliers offer temporary price discounts in the private market to promote their products. Normally, it would be expected that these promotions would be extended to VAMKC as well. However, because a temporary price cut must be extended for the entire contract year, suppliers are reluctant to offer such discount prices to VAMKC.

Even the requirement that prices cannot be increased during the course of a contract year has indeterminate effects on procurement costs. On the one hand, such a requirement protects those who buy through VAMKC from price increases for the contract year. On the other hand, it is possible that suppliers charge a higher price to begin with as a form of insurance against their margins' being eroded by cost increases. It is not possible to determine the direction of the total impact of the firm fixed-price clause.

Public Disclosure Requirements

By law, the public has access to the prices at which VAMKC procures medical equipment. There is both theoretical and empirical support for the view that this results in higher procurement costs for VAMKC. The reasoning is that the benefits that a firm receives from cutting its price below that of its rivals are in part a function of the "retaliation lag," the length of time before rivals learn of the price cut and cut their own prices in response. The price disclosure requirements have the effect of reducing the retaliation lag, and therefore act to discourage such price cutting in the VAMKC market.

In addition, because private buyers of medical equipment also have access to the price data, the fact that the VAMKC price may serve as the buyer's target in pricing negotiations can also inhibit price cutting in the VAMKC market. Suppliers in the market for X-ray equipment, nuclear medical equipment, patient monitoring, and hemodialysis equipment indicate that prices offered to VAMKC are higher than they would be in the absence of the contract disclosure requirement. In markets where the disclosure requirement has not affected pricing, the perceived reason is that pricing information is widely available from other sources.

No Volume Commitment

VAMKC does not make specific volume commitments to its suppliers, who contract to provide equipment at preestablished prices. In most equipment categories (other than X-ray and nuclear diagnostic equipment), the absence of a volume commitment is a major factor in supplier pricing behavior.

There are several reasons why a volume commitment appears to be very important in some industries and unimportant in others. First, the importance of a volume commitment seems to depend on whether the equipment is typically "custom made" or purchased from supplier stock. If equipment is purchased from stock and is fairly homogeneous, a volume commitment can provide reductions in manufacturing cost that can be passed on to the buyer in lower prices.

Second, the importance of a volume commitment seems to depend on whether the equipment is expensive or inexpensive. If the equipment is inexpensive, the costs of preparing contracts and marketing the product to buyers are higher relative to the purchase price of the equipment. In this situation, the cost savings that come with a volume commitment are more significant, and the commitment allows some of these savings to be passed on to the buyer. Some suppliers indicated a willingness to lower prices by 5 to 10 percent in exchange for a volume commitment. Even for relatively expensive devices, such as ultrasound equipment, one supplier stated that a group purchase of 15 to 20 units would suffice for a larger price discount than now offered.

Most Favored Customer Clause

Under the terms of a VAMKC contract, suppliers are not allowed to sell their equipment under a similar contract to any private buyer at a price lower than that offered to VAMKC. If a lower price is offered to a private buyer, the vendor must lower the VAMKC contract price to the same level for the balance of the contract. Because VAMKC must be offered a price as low as that offered to any private buyer, the most favored customer clause helps ensure that the VAMKC's clients benefit from competition among suppliers in the private hospital market.[4]

Although the strictness with which the most favored customer clause is interpreted varies from one equipment category to another, it almost certainly has the effect of reducing VAMKC equipment procurement costs. The policy can also have a powerful impact on private buyers. In a few markets, private buyers are offered lower prices than VAMKC when they make contractual volume commitments, on the grounds that the contracts are not like the VAMKC contract. In these markets, the impact of the most favored customer policy is obviously less than it is in other markets.

However, in many cases the most favored customer clause may have the effect of increasing prices that private buyers must pay for medical equipment. Specifically, both buyers in the VA and suppliers indicated that prices were affected in the markets for X-ray, nuclear diagnostic, ultrasonic, and patient monitoring equipment, as well as for CT scanning devices.

Reluctance To Procure Mixed Systems

Despite the absence of a formal restriction, VAMKC has exhibited a reluctance to purchase medical equipment systems in which items of equipment produced by several different companies are interconnected. There are several reasons for this, the most important of which are the difficulties of assigning financial responsibility for repairs under warranty and of determining responsibility for the actual interconnection of the equipment. Unfortunately, VAMKC's policy can have the effect of practically eliminating many smaller companies from the procurement process, and may, as a result, cause higher initial procurement costs for the VA. The reluctance to purchase mixed systems is based on actual procurement experience, but the practice merits periodic review to determine if it saves costs over time.

Procurement by VA Medical Centers

Actual purchase of medical equipment and supplies is carried out by local supply officers located in each of the VA medical centers. Although VAMKC is responsible for centrally managing and negotiating contracts for items commonly used by the medical facilities, individual VA medical centers make their own purchase decisions. To the extent that the medical centers use the centrally managed supply channels, lower product costs are available to them through the combined VA-wide quantity purchases. However, the VA hospital system is actually a loose confederation of semiautonomous institutions in terms of device procurement, thereby reducing many of the advantages available to it as a large market power.

Increasingly, the VA medical centers have purchased their supplies and equipment on the open market rather than using central supply channels.

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[4] As noted above, VA suppliers may offer lower prices to private buyers if contract terms, such as volume commitments, differ.

Whereas in the early 1960s, only about 10 percent of their medical supplies were acquired through local-level open market purchases, in fiscal year 1982, 39 percent of total purchases were made on the open market (131,428). Table 39 shows the relative contribution of each of the VA's supply channels to the total purchases made by the VA medical centers. The increase in open market purchases has resulted primarily from an implicit policy within the VA system to allow individual physicians the freedom to choose their own medical equipment and supplies.

Both a 1980 General Accounting Office report (335) and the recent report by the President's Private Sector Survey on Cost Control (Grace Commission) (131) concluded that the VA was unnecessarily paying more for supplies and equipment because of the large percentage of purchases being made on the open market. Finding that the VA defeats the price advantages available to it through greater item standardization and volume purchases, the reports called for greater central purchasing through an expansion of national contracts.

Table 39.—Veterans Administration Medical Center Purchasing Source Priorities, Fiscal Year 1982

Supply channel	Veterans Administration priority ranking	Approximate annual purchases ($ in millions)	Percentage of total
Veterans Administration excess	1	NA	NA
Veterans Administration supply depots	2	$197.9	15.3%
Other Government excess	3	0.4	—
Federal prisons and correctional institutions, blind-made and severely handicapped products	4	1.0	1
General Services Administration stock	5	34.1	2.7
Veterans Administration decentralized contracts	6	41.4	3.2
Federal Supply Service contracts	7	434.4	33.6
Open market purchases	8	498.2	38.5
Other	none	86.0	6.6

NA indicates information not available.

SOURCE: U.S. Veterans Administration, 1983.

ADOPTION AND USE

Rehabilitative Devices

Unlike coverage policies under Medicare and Medicaid (see ch. 3), the VA's policy is to make available all rehabilitative technologies and devices that are suited to the needs of millions of eligible veterans. Of course, determinations about circumstances and clinical needs still need to be made, but VA policy is to provide blind veterans with the necessary services and devices to overcome their disability and to provide disabled veterans with all technologies and devices deemed medically necessary. An issue of mounting concern to the VA users and policymakers is the cost of this policy of covering all available technologies and devices (352).

The range of rehabilitative medical devices provided by the VA health care system is enormous. There are, for example, over 300 types of sensory aids provided for blind people (39). In fiscal year 1982, about 34,000 hearing aids and over $80 million in prosthetic services were made available to eligible veterans (426). In the area of rehabilitation services, more than 80 percent of eligible veterans have non-service-connected disabilities, with a large proportion suffering from the effects of chronic diseases associated with aging.

Determinations of individual veterans' needs are made at the clinical level, within the patient-physician relationship. Usually, the health professional caring for the patient requests procurement of needed medical devices through the VA Supply Service in an individual VA medical center. However, procurement of prosthetic devices is handled differently. All prostheses, from eyeglasses to motorized wheelchairs, are obtained through the prosthetic representative, a veteran with a service-connected disability hired by the VA to serve as the purchasing agent.

Clinical teams of physicians, physical/occupational therapists, prosthetists, and prosthetic representatives meet with the veteran to decide which prostheses should be prescribed. They then choose from among the possible range of devices that have been approved by the Prosthetic and Sensory Aids Service.

Photo credit: Amigo Sales, Inc.

This woman is using an Amigo power wheelchair. For the provision of power, as opposed to manually operated, wheelchairs to veterans, the VA requires the approval of an individual VA medical center.

Because of the relatively high volume of devices handled by the Prosthetic and Sensory Aids Service, the other VA rehabilitative services, such as the Spinal Cord Injury Service, have come over the years to use that service as a central purchasing clearinghouse for their own supplies and devices. This situation has involved the Prosthetic and Sensory Aids Service in ordering devices such as pacemakers that have very little to do with the actual functions of the prosthetic representatives. Although this manner of handling supply procurement has helped hold down the personnel requirements of the other services, it has also placed increased fiscal and administrative burdens on the Prosthetic and Sensory Aids Service (93,439).

The budget of the Prosthetic and Sensory Aids Service has tripled in 8 years to $84 million, and it has been projected to reach $500 million annually in 4 to 5 years (93). One of the major reasons for the steep rise in costs has been the increasing purchase of the sophisticated technology that is now available for use by disabled veterans. Another reason has been the growing population of veterans whose mobility and senses are affected by the aging process (426). Probably the most important reason for the budget increases, however, is that, by law, the provision of prosthetics to veterans is unlimited. The growth in these costs has in turn taken resources from other parts of VA health care.

Influence of Social, Political, and Economic Factors

Political and social forces greatly influence the adoption and use of medical devices within the VA health care system. As mentioned earlier, for example, veterans' service organizations frequently approach their local VA hospital administrators about buying the latest technologies for their veteran constituencies. As another example, Thompson has argued that decisions about VA hospital construction depend more on access to medical school skills and resources than on other concerns, such as promoting access of veterans to medical care (298).

The VA medical centers have tried to make their institutions hospitable places for teaching and research. In this regard, medical schools have often successfully encouraged VA hospitals to seek the latest in equipment and specialized facilities. A study by the National Academy of Sciences noted marked proliferation of special care units in VA hospitals by the end of the 1970s (224).

Health planning and utilization review agencies (see ch. 6) have no authority over VA medical centers. The National Health Planning and Resources Development Act of 1974 (Public Law 93-641) gave the VA voting membership on State health coordinating councils and on local health systems agencies, but VA medical centers submit applications for new construction or equipment to the local health planning agencies on a strictly voluntary basis. Likewise, the VA has successfully resisted efforts to place its hospitals under the authority of utilization and quality control peer review organizations, which perform utilization reviews for the Medicare and Medicaid programs. Instead, the VA moved to establish its own Health Services Review Organization to foster quality assessment and utilization review.

Political and economic forces have acted to constrain the adoption and use of medical devices. The VA's overall health care budget has been stable during the past few years, and the tight budget has undoubtedly served as the most powerful rein on overadoption. In addition, the congressional appropriations committees and other oversight groups have frequently opposed the VA's autonomy in decisionmaking with regard to resource allocation. In 1978, for example, efforts by the VA to supplement 24 existing CT scanners with 13 additional scanners were criticized by the General Accounting Office, and congressional resistance eventually prompted the VA to withdraw the request (330). As another example, the Office of Management and Budget successfully pressured the VA to reduce its supply of hospital beds from roughly 121,000 in 1964 to fewer than 90,000 by 1980 (298).

Overall, the concurrent social and political pressures that develop incentives to overadopt devices in some areas, while constraining expenditures in others, have had important implications over time. The often sporadic patterns of adoption and use of devices and other technologies and patterns of care by the VA have led to a distribution of resources that may not be equitable or efficient across geographic areas or types of facilities. Thus, for example, although the VA is an international leader in such areas as cardiac care and radioisotopes, fewer than one-third of the VA medical centers had CT scanners in 1983 (150). In fact, an extensive study by the National Academy of Sciences in 1977 found ample evidence of maldistribution in terms of equipment, basic and specialized services, staffing, and number of beds (224).

Strategic Planning

There is every indication that with regard to medical device and technology acquisition, the VA is in transition. Perhaps the most significant initiative undertaken by the agency in relation to medical equipment adoption and use has been the implementation since fiscal year 1981 of Medical District Initiated Program Planning (MEDIPP). The MEDIPP process is an attempt to create a decentralized long-range "strategic planning system" in which major plan development responsibilities are assigned to the VA's 28 medical districts.

The VA has recognized that past resource-based planning and management approaches are no longer feasible in an era of stable or declining health care budgets and changing demands by its aging veteran population. Although there will be increased demand for services in the short term as the size of the elderly veteran population grows, in the long-term, demand for services will decline as this largest group of beneficiaries now entering old age dies.

Because the future certainly holds cutbacks or termination of specific services or facilities, understanding and acceptance within the VA and its constituencies are important factors in the eventual success and implementation of the MEDIPP process. A key element of the new planning process is its emphasis on involving administrative and clinical personnel at several levels within the VA Department of Medicine and Surgery (429).

The MEDIPP process consists of a cycle of events throughout the fiscal year. It begins with direction by the VA's Chief Medical Director on broad-based issues, objectives, and goals for the future. Each VA medical district then appoints a District Planning Board and staff to develop a district plan within the overall framework of systemwide goals. The district plans include a demographic analysis, a workload forecast, and a review of the local resources that are submitted by the VA health care facilities within its jurisdiction. Finally, the district administrators and councils review and approve the district plans and submit them to the VA Central Office (218, 426,432).

The first MEDIPP cycle ended in November 1982 and covers fiscal years 1985 to 1990. An internal VA study examined the relationship between technology needs and the MEDIPP plans that were submitted (45). It found that most of the medical districts were using the MEDIPP process to request the purchase of specific major medical devices and equipment, in addition to proposals for the creation, expansion, or dismantling of services. In effect, the MEDIPP process could serve as a vehicle for identifying and monitoring the need and demand for various types of major medical equipment. The study also found that VA administrators and planners ranked the issue of device acquisition (and the larger issue of medical technology) fourth in importance among 50 VA-wide issue areas.

These findings confirm and reinforce the potential utility of the MEDIPP process, not only as a planning tool, but also as an early warning and tracking system for major equipment adoption and use. As new device and equipment requests begin to surface through medical district plans, a coherent and well-focused program of evaluation could be initiated (45). Such evaluations could include broader technology assessment issues such as devices' cost effectiveness in the overall delivery of care.

Another new process that may affect medical device adoption and use is setting the budgets of VA medical centers on the basis of diagnosis related groups (DRGs) (103). Although the VA has budgeted prospectively because of the congressional appropriations process, the use of a case-mix measure such as DRGs is intended to distribute the available funds more rationally among the medical centers.

DRGs classify patients according to principal diagnosis, presence of a surgical procedure, age, presence or absence of significant comorbidities or complications, and other relevant criteria. The new Medicare prospective payment system for hospitals is also based on DRGs (see ch. 3). Both the VA budgeting system and the Medicare payment system use similar mathematical models to assign patients to DRGs and to allocate resources among DRGs.

Data sources included all VA discharge abstracts, costs across different service categories (medical, surgical, psychiatric), the current 470 DRG model,[5] and the New Jersey Reimbursement Schedule. Since the VA has no patient-based method of assigning costs, the VA used New Jersey cost data to assign relative DRG weights to the VA discharges, and these weights were used for allocation decisions (104).

The VA expects the new budget method to encourage more efficient use of resources within hospitals and to distribute the funds more rationally because hospitals will receive funds on the basis of case mix instead of historical budgets. DRGs are also to be used in VA utilization review and quality assurance programs (104). Adoption of medical devices will be more affected by MEDIPP, although DRG budgeting will probably affect use of the devices.

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[5] There are 467 DRGs, plus 3 that require special treatment of the data: DRG 468 flags an operating room procedure that is unrelated to the principal diagnosis; DRG 469 represents a patient with a diagnosis that is valid as a principal diagnosis, but not acceptable as a principal diagnosis; and DRG 470 indicates invalid data.

DISCUSSION AND POLICY OPTIONS

The VA has the potential to use its extensive procurement to influence the type and price of medical devices that are developed and marketed. Although the VA appears to have obtained lower prices because of purchases from least-cost suppliers, other procedures such as more standardized purchases and volume commitments to device suppliers might result in greater price reductions. In addition, R&D evaluation, and procurement have been separate, unintegrated activities within the VA. The potential of the VA's leverage has not been realized in stimulating the development of certain types of devices. Nor have the results of the VA's own R&D and evaluation activities been systematically incorporated into the VA's procurement and adoption decisions.

In an attempt to coordinate these activities, the VA is discussing an administrative reorganization that would put the Rehabilitation R&D Service, the Prosthetic and Sensory Aids Service, and the VA Prosthetics Center in one line (39). The following sections offer options for specific improvements within the areas of R&D, testing and evaluation, procurement, and adoption and use of medical devices by the VA health care system.

Research and Development

To give increased focus to its rehabilitation research efforts, the VA in 1973 organized the Rehabilitation R&D Service. More recently, the VA has established rehabilitation R&D centers that are affiliated with engineering schools (two at present, six more planned by 1986) for broader outreach. However, when inflation is taken into account, the VA's funding commitment to R&D has been stable or declining. Veterans' service organizations have expressed concern about effective cutbacks in R&D budgets, especially in the areas of prosthetics research and research on sensory aids for the blind and hearing-impaired.

Option 1: Increase the VA's funding for rehabilitative research that is focused on longer term development of devices.

The appropriate placement of rehabilitation R&D of this type could be at the rehabilitation R&D centers, at the VA Prosthetics Center, or at both, depending on the goals of the Rehabilitation R&D Service. The rehabilitation R&D centers at Hines and Palo Alto are connected with their local engineering communities. The primary mission of these centers is to apply advanced technology to assist physically handicapped veterans with the goal of commercialization of the devices.

The VA Prosthetics Center combines the development of commercially available prosthetics and sensory aids with clinical activities through an integrated management. Its engineers and professional personnel work closely with patients in several VA medical centers, customizing prosthetics and generally applying the expertise of the research engineers to present problems. In addition, within a fixed budget, any decision to channel more funds to long-term rehabilitative research would require a determination that such research was more worthwhile than other uses of these funds.

Testing and Evaluation

The responsibility for testing and evaluating medical devices is divided among several VA organizational units. The Rehabilitation R&D Service evaluates rehabilitative prototype devices that are still in the developmental stage. Once the medical devices are commercially available, the responsibility for evaluation is split between the Prosthetic and Sensory Aids Service for rehabilitative devices and the Office of Procurement and Supply for all nonrehabilitative devices, equipment, and systems purchased by the VA. The Disabled American Veterans organization has called the evaluation system fraught with inefficiencies and communication breakdowns. Efforts of the various organizational units have sometimes overlapped and unnecessarily duplicated each other.

The absence of internal planning and coordination for its evaluation activities has generally been recognized by the VA. Recently, the Rehabilitation R&D Service created the Rehabilitation R&D Evaluation Unit to coordinate and improve testing of prototype rehabilitative devices, and the Prosthetic and Sensory Aids Service formed the

Prosthetic Technology Evaluation Committee to develop a formal evaluation and coordination process for commercially available rehabilitative products. The Office of Procurement and Supply established the Testing and Evaluation Staff in 1976 to provide evaluations of nonrehabilitative medical devices, equipment, and supplies. The evaluations are incorporated into national procurement contract requirements, but are advisory only. Purchasing decisions still rest with individual hospitals.

These improvements in evaluation processes may result in more appropriate adoption and use of medical technologies by the VA. They may also result in better adoption and use of medical technologies by other Government agencies and by the private sector through the dissemination of evaluation findings. Although it is premature to assess these newly created committees and programs, options for specific improvements are presented below.

Option 2: Encourage the expansion of field testing of rehabilitative devices by the VA Prosthetics Center.

The VA Prosthetics Center is charged with performing "compliance testing" on all commercially available rehabilitative devices for the Prosthetic and Sensory Aids Service. Devices can undergo either special laboratory testing or field testing at VA medical centers, or both.

Field testing is advantageous in that it allows an evaluation to more accurately assess a device's usefulness to the veteran population. Because of organizational difficulties, however, the VA Prosthetics Center has never used field testing to its fullest possible extent.

Until fiscal year 1984, there was no line authority from the VA Prosthetics Center or from the Prosthetic and Sensory Aids Service to the VA medical centers, where the field evaluations are performed. Absence of line authority had resulted in a loss of control by the testing units over adherence to protocols and reporting of evaluation data and often created initial resistance to cooperation in device studies.

The new Prosthetic Technology Evaluation Committee, which includes representatives from all the concerned organizational units within the VA, is mandated to classify devices into groups which will determine the types of evaluations that the devices will undergo. This committee will need to establish some internal control over the VA medical facilities to assure adherence to evaluation protocols and the collection of accurate data during expanded field studies.

Option 3: Require the VA to conduct more comparative evaluations before purchasing commercially available devices.

Evaluations of devices by the Testing and Evaluation Staff of the VA's Office of Procurement and Supply are usually internal "consumer research" efforts that take the form of user surveys. Although not scientifically rigorous, they do provide an information base for purchasing by individual VA medical centers. The VA estimates that only about 20 percent of its medical centers strictly adhere to purchasing decisions based on these evaluations. However, results of the evaluations are also routinely requested by private hospitals, nursing homes, and State and local governments.

Evaluative information would be improved if more comparative evaluations that identified the positive and negative consequences of purchase and use of particular products were undertaken. Product quality features—such as safety, durability, and performance—could be more closely matched with cost considerations. More valid results would also result from evaluating larger samples.

Although the VA currently prohibits explicit comparison of one product with another, the Testing and Evaluation Staff has attempted some group evaluations of classes of devices. The primary obstacle to expanding these efforts has been staffing and budgetary constraints. These constraints might have to be eased in order to provide better evaluative information for VA purchasing decisions.

Procurement

Available evidence indicates that the VA's centralized procurement programs, through various contract and distribution mechanisms, have for the most part created favorable prices for medical equipment and supplies for the VA medical centers. Some policies, like the most favored customer clause, almost certainly reduce the VA's equipment procurement costs, but at the same time have the effect of increasing the prices that private buyers must pay for medical equipment. At least one policy, the VA's refusal to provide volume commitments to contractors, probably results in the VA's not getting the lowest prices possible for some medical devices. Other policies are more ambiguous with respect to their impact on procurement costs.

A greater problem for the VA is the extent to which the VA medical centers fail to use centralized procurement channels. VA medical facilities now purchase about 39 percent of their supplies and equipment on the open market, up from 10 percent in the early 1960s. This individual purchasing reduces the advantages available to the VA as a large institutional buyer.

Option 4: Encourage the VA to increase the proportion of its procurement of equipment and supplies by centralized contracts to realize lower costs from the VA's leverage in the marketplace.

Combining quantity purchases of equipment and supplies on a national basis through centralized procurement could result in lower product costs through price discounts. Centralizing more device purchases could increase the VA's buying power and could lead to even greater price discounts.

There are problems, however, in getting physicians to support more centralized procurement. As part of the effort to retain physicians on staff, it has been the practice of the VA since the 1960s to allow physicians to choose their own brands of medical equipment and supplies. The difficulty of achieving physician/user acceptance of one specific type of medical equipment is a substantial obstacle to increasing centralized procurement.

Use of consensus groups might be one mechanism to help physicians reach agreement, or perhaps hospital administrators could be given greater authority. The extent of disagreement among physicians regarding the desirability of particular brands or models of medical equipment varies depending on the type of equipment, the number of manufacturers, and other less tangible factors.

Adoption and Use

Because of incentives to overadopt in some areas and concurrent financial constraints in others, the VA has experienced sporadic patterns of adoption and use of devices and other technologies that have led to a distribution of resources that may not be equitable or efficient across geographic areas or types of facilities. For example, some types of major medical equipment, such as CT scanners, may have been underadopted by the VA because of political pressures to contain costs. On the other hand, by statute, the provision of rehabilitative devices to veterans is unlimited. As a result, resources have been drained away from other parts of the VA's health care budget as costs for rehabilitative devices have expanded.

Option 5: Encourage development of comprehensive evaluations of major medical equipment as part of the VA's strategic planning process.

The VA lacks systematic methods for distributing major new medical equipment among its medical centers and within its districts. The new MEDIPP (Medical District Initiated Program Planning) process is an attempt to create a decentralized long-range strategic planning process in which plan development responsibilities are assigned to the VA's 28 medical districts. The MEDIPP process could serve as a vehicle for identifying and monitoring the need and demand for various types of major medical equipment. A coherent, focused evaluation program could then be initiated to guide the adoption and use of new medical equipment within the VA.

In June 1983, the VA's Chief Medical Director formed a High-Technology Assessment Group to determine future VA policy on the acquisition of major new technologies. Comprehensive technology assessments have not as yet been used extensively in the VA health care system The VA continues to face the constraints of stable or declining health care budgets, and the use of analytical methods to evaluate the health and economic effects of technologies could assist in developing information for allocating health care resources more effectively and equitably than in the past. The process of conducting such evaluations would raise relevant issues and the results might provide useful information. But decisions about device adoption and use would still require judgments about factors such as equity and ethics that are difficult to incorporate into an analysis.

Appendixes

Appendix A.—Method of the Study

On June 17, 1982, OTA's Technology Assessment Board approved the assessment entitled "Federal Policies and the Medical Devices Industry," to begin September 1, 1982. The proposal stated that the study would address gaps in basic information about the medical devices industry and would examine present and proposed Federal policies that influence the sector.

During the planning period that preceded the study, OTA staff consulted with industry trade associations, consumer groups, and Federal agencies for two purposes: to seek suggestions for members of the study's advisory panel and to identify issues in the field. An advisory panel guides OTA staff in selecting material and issues to consider and reviews written work, but the panel is not responsible for the content of the final report.

The advisory panel selected for this assessment consisted of members from different segments of the industry—large and small companies, medicine, nursing, hospital administration, economics, policy analysis, law, and consumer advocacy. Richard R. Nelson of Yale University chaired the panel, and two other members, Joyce Lashof and Rosemary Stevens, served concurrently on the standing Health Program Advisory Committee. At the beginning of the study, the staff compiled a bibliography and gained familiarity with major issues and with sources of data on companies that make up the industry. This effort was aided by a background paper prepared by Anthony A. Romeo and by a September meeting with company executives arranged by the Health Industry Manufacturers Association. The study was also considered at the September meeting of the Health Program Advisory Committee, which advised that the perspectives of consumers and of different segments of the industry be sought.

At the first panel meeting, on October 7, 1982, discussion centered on the overall study plan and on major policy areas, especially payment for the use of medical devices and premarket regulation by the Food and Drug Administration (FDA). In order to illuminate certain policies and to gain greater insight into certain segments of the industry, it was decided to select specific medical devices for more detailed case study. The panel discussed criteria for selecting the case studies, including the importance of certain policies. Also raised was interest in the process by which devices are developed and brought to market.

Following the panel meeting, OTA staff selected six case studies: the Boston elbow, contact lenses, hemodialysis equipment, nuclear magnetic resonance imaging, technologies for urinary incontinence, and wheelchairs. It was also decided to produce a separate technical memorandum on the policies of the Veterans Administration (VA) concerning medical devices, since the relevant policies of this health care delivery system are both extensive and separate from others. The technical memorandum was to be prepared by OTA staff, and the case studies and other background papers by contractors outside of OTA.

On the basis of advice from the Health Program Advisory Committee and the advisory panel for this assessment, two workshops were held at OTA in December 1982: one on December 7 on the purchase and use of medical devices and the other on December 15 on research, development, and marketing of medical devices. Suggestions for organizations and individuals to participate were solicited from a wide range of interested parties.

The first workshop, which was chaired by Louise Russell from the advisory panel, consisted of people involved in different facets of the purchase and use of devices, including multihospital organizations, municipal hospital administration, hospital administration in the VA, hospital bioengineering, handicapped people, and physicians of different specialties (see app. B). Although their interests varied, the participants shared the need for better evaluative information on devices, concern about postmarketing surveillance of device problems and standard setting for devices by FDA, and interest in devices that meet a clinical need instead of overly sophisticated ones.

The participants at the second workshop, chaired by Richard Nelson of the advisory panel, were involved in the invention, development, and marketing of devices as individual inventors, managers in large companies, university researchers, or marketing representatives (see app. B). Discussion in this workshop centered on problems in commercializing devices, especially in securing funding to develop prototype devices; the role of Federal regulation, including FDA, VA, and the Patent Office; the role in the development process of different actors, such as individual inventors, small firms, and large firms. On the basis of this discussion, the OTA staff decided to compile vignettes on the development process from inventors of different devices and from different organizations.

The staff next prepared a draft status report, which presented information gained up to that point in the study on the industry and on Federal policies regarding payment, FDA regulation, the VA, research and development, patents, and international trade. The status report was the major topic of the second panel meeting held at OTA on March 3, 1983. The discussion pointed out the advisability of focusing the final report of the assessment on policies specific to medical care and, within those policies, on matters related to medical devices.

Considerable discussion at the panel meeting also surrounded FDA regulation of medical devices. Because of the importance of this policy area, a workshop on regulation under the 1976 Medical Device Amendments was held at OTA on May 19, 1983. Participants included attorneys and other policymakers from Federal agencies, consumer groups, and private firms who had been involved in drafting and implementing the legislation (see app. B). The workshop discussed the intentions of the framers of the law, the evolution of the bill as it went through the legislative process, and its implementation as practical problems were faced by FDA.

At its third meeting, on August 4, 1983, the advisory panel discussed the revised draft of the status report as well as drafts of a case study and background paper that had been received. The panel noted that the report would have to take into account the changes in payment occasioned by Medicare's forthcoming use of diagnosis related groups. The final draft of the status report was sent to the requesting congressional committees in order to inform them of the progress and components of the study.

During the fall and early winter, drafts of the remaining case studies and background papers were received, sent to the advisory panel and other experts for review, and revised by contractors. The material was therefore available to OTA staff as they were preparing the first draft of the final report. In March 1984, that draft was sent to the advisory panel, the Health Program Advisory Committee, and 75 other reviewers who are experts in fields related to different aspects of the study.

The draft report was discussed at the March 31 meeting of the Health Program Advisory Committee and at the fourth and final meeting of the advisory panel on April 3. The committee advised that more note be taken of devices for which adoption and use have been insufficient. The advisory panel concentrated on the summary chapter, FDA regulation, and policy options. After the meeting, OTA staff revised the final report based on comments received from the panel and other reviewers and in early May sent the revised summary chapter to the advisory panel and the Health Program Advisory Committee. The revised report was reviewed within OTA and in mid-May was submitted for approval to the Technology Assessment Board.

Several documents are being published in connection with the assessment: the main report (of which this appendix is a part), a booklet summarizing the main report, a technical memorandum on policies of the VA, a background paper of inventors' vignettes, and six case studies. In addition to this report and the summary, the following publications will be available through the U.S. Government Printing Office:

- *Inventors' Vignettes of the Development of Medical Devices*, edited by OTA staff.
- *Medical Devices and the Veterans Administration*, by OTA staff.
- *Technologies for Managing Urinary Incontinence*, by Joseph Ouslander and Robert L. Kane, University of California, Los Angeles.
- *The Boston Elbow*, by Sandra J. Tanenbaum, Massachusetts Institute of Technology.
- *The Contact Lens Industry: Structure, Competition and Public Policy*, by Leonard G. Schifrin, College of William and Mary.
- *Nuclear Magnetic Resonance Imaging Technology: A Clinical, Industrial, and Policy Analysis*, by Earl P. Steinberg and Alan B. Cohen, Johns Hopkins Medical Institutions.
- *The Hemodialysis Equipment and Disposables Industry*, by Anthony A. Romeo, University of Connecticut.
- *The Market for Wheelchairs: Innovations and Federal Policy*, by Donald S. Shepard and Sarita L. Karon, Harvard School of Public Health.

In addition, papers were prepared on contract to OTA to provide background information for the main report and are available through OTA in limited quantities:

- "Capital Markets, Government Regulation, Tax Policy, and the Financing of Medical Device Innovations," by James R. Barth and Joseph J. Cordes, with Michael Bradley, George Washington University.
- "Governmental Barriers to International Trade in Medical Devices in the United States, United Kingdom, France, the Federal Republic of Germany, Canada, Japan, and Mexico," by Kaye, Scholer, Fierman, Hays & Handler, Washington, DC.
- "Innovative Activity in the Medical Devices Industry," by Anthony A. Romeo, University of Connecticut.
- "Medical Device Standards and International Trade," by Kornmeier, McCarthy, Lepon & Harris, Washington, DC.
- "The Impact of Federal and State Regulatory Programs on the Ambulatory Laboratory Testing Industry and the Demand for Instrumentation," by Hope S. Foster, O'Connor & Hannan, Washington, DC.
- "The Relationship of FDA, PHS, and HCFA Regarding Medical Device and Organ Transplant

Technologies," by Dennis J. Cotter, Georgetown University.
- "The Role of the Government in the Research, Development, and Commercialization of Computed Tomography (CT) Scanning and Nuclear Magnetic Resonance (NMR) in the United Kingdom," by John Hutton, University of York, England.
- "Veterans Administration Procurement and the Market for Medical Equipment," by Ralph M. Bradburd, Williams College.

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Appendix C.—The Innovative Process in the Medical Devices Field

Introduction

As a society, we value technological progress—the continual "introduction to practice of new and more useful ways of serving human purposes" (262). In the health field, technological progress is often embodied in the introduction of new medical devices. Despite its importance, there has been little systematic investigation of the process of technological change for medical devices. How and by whom do medical devices get developed? And what factors influence their development?

There are, of course, many stories about the introduction of specific new devices, such as electronic fetal monitors (410), gastric freezing (114), gastroendoscopes (448), and computed tomography (CT) scanners (348). These individual cases demonstrate the diversity of developmental pathways taken. They suggest that simple generalizations of the process are impossible. Yet, some elements of the process may be common to all medical devices and, indeed, to all new technologies.

The basic unit of technological change is innovation—a new device, product, or process introduced to practice for the first time (223,182). Innovation is also widely used to refer to the process by which technological change occurs (232). In this OTA assessment, "innovation" refers to the newly introduced technology and "innovative process" to the process by which innovations find their way into practice. This appendix explores the process of technological change in general, with emphasis on the questions of who develops innovations and under what conditions the innovative process occurs.

Innovations are valued for their capacity to increase productivity or the quality of consumption (274). Those innovations largely affecting production processes have been called process innovations, while those intended for sale are product innovations (438). New medical devices are product innovations, although they may change the process of medical care.

One important view of the innovative process is that it consists of four essential functions (274):[1]

- Invention—the act of insight by which a new and promising technical possibility is recognized and worked out (at least mentally and perhaps also physically).
- Development—the sequence of detail-oriented technical activities, including testing by trial and error, through which the original concept is modified and perfected until it is commercially viable.
- Entrepreneurship—the decision to go forward with the effort, the organization of it, and the securing of funding for it.
- Investment—the act of risking funds for the venture.

For the innovative process to succeed in producing an innovation, each of these four components is necessary, but the mix may differ widely among applications. Some innovations are the result of sudden insights, with little developmental work needed; others may require a laborious and slow development phase with high levels of investment. Nevertheless, all innovative processes contain each of these components to a greater or lesser extent.

When and Where the Innovative Process Occurs

Theories of innovation rest largely on underlying views of the innovative process as either deterministic, individualistic, or serendipitous (182). The deterministic view holds that innovations come forth when the conditions are right; the individualistic theory stresses the importance of the innovator (an individual or organization) in bringing forth and carrying through an idea; and the serendipity approach stresses the stochastic nature of the process of technological change (182).

There is, of course, some truth in each of these approaches. Variability, complexity, and uncertainty are the hallmarks of innovative processes (231). These three factors have substantial influence on the effectiveness of policies intended to affect the rate and direction of technological change (232). Innovative processes vary widely among industries and institutions and are not well characterized by simple methods. However, a brief description of how medical and surgical procedures that use medical devices come into being may highlight the characteristics of the innovative process in medicine.[2]

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[1] There are several other models of the "innovative process" that focus on the chronological stages rather than on critical functions. Schumpeter defined technical change as having three steps: invention, innovation, and imitation (or diffusion) (274). A recent study of the Organization for Economic Cooperation and Development has identified four stages of innovation: conception, reduction to practice (i.e., prototype), startup, and expansion (diffusion) (236). These alternative characterizations of the innovative process do not contradict one another; they highlight the points in the process of interest to each author.

[2] The description presented here is adapted from appendix D of an OTA report entitled *Strategies for Medical Technology Assessment* (351).

Medical and surgical procedures, which often involve the use of medical devices, usually begin as user-generated (e.g., physician-generated) innovations. An innovative procedure may involve the modification of an existing procedure (usually in accompaniment with modifications of the devices being used) for application to a new use.

Innovations in procedures frequently arise in academic or academic-associated centers, where physical and professional resources are readily available; a research, innovation-seeking atmosphere is encouraged; and contacts with others in the field extend not only nationally, but also globally. Innovators in such settings know how to present the innovations in a manner that will be technically acceptable and have the prestige that gives them access to professional meetings and journals to publicize their results. Their presentations and publications not only diffuse the innovation to a wider audience, but more importantly, begin to legitimize it. Depending on the claimed innovation's nature, usually defined in terms of how the innovation will revolutionize or at least substantially influence the related area of medical or surgical practice, other academic centers will begin to pursue it.

At some point in the innovative process, a prototype device must be developed. This activity may occur in a variety of settings including the academic center, a hospital, a medical device firm, or even a home laboratory. The development and refinement of a prototype can be a costly and time-consuming part of the innovative process.

At this point, several U.S. Government agencies may enter the picture. The National Institutes of Health (NIH) may provide support for the innovator and researchers in other health centers through randomized clinical trials, most likely conducted in some of the clinical research centers funded by NIH. A new device or modification of an existing device requires the Food and Drug Administration's (FDA) approval. Increasingly, FDA approves the use of investigational devices for limited testing at the same centers that NIH supports as clinical research centers (or at least to the health institutions in which these designated centers are located).

FDA must make a determination of safety and efficacy for market clearance of the device under review. FDA will often make its decision long before NIH reaches a decision and terminates funding for the clinical trials. FDA's decision may rest on the narrow question of the technical functioning and safety of the device. Release of the device to the general market, once premarket approval is given, also tends to speed up the diffusion of the procedure that NIH may be studying.

This result, in turn, places more pressure on the Health Care Financing Administration (HCFA) to reimburse for the procedure. Sooner or later, HCFA may receive a request for reimbursement of the new procedure and will consider information from any clinical trials for evidence of safety and efficacy, but only after the device has been approved for marketing by FDA.

Conditions Affecting the Innovative Process

Despite the variability and uncertainty of the innovative process, there are institutional and other contextual conditions that may influence the process in systematic ways. These conditions fall into four categories:

- conditions affecting the market for the innovation,
- conditions affecting the ability to appropriate the benefits of the effort to produce the innovation,
- conditions affecting the availability of resources to invest in the innovation, and
- conditions affecting the availability and organization of technical and entrepreneurial know-how.

Conditions Affecting the Market for Innovation

The market for an innovation depends on the willingness of each potential user to pay for its benefits. If a new medical device is to survive after a trial, it must be perceived as worthwhile by the people or organizations who will decide whether or not it will be used (232). Thus, the perceived need for and potential benefits of a new device determine the size of the market. Even the "user/innovator," the individuals or organizations that go about solving their own problems through technological change (446), are likely to assess the potential benefit of the innovation to themselves and to others in their decisions to devote time and resources to solving a problem.

Both the size and organization of the market can be important in determining the willingness to pay for useful innovations (268). For example, potential economies of scale in the production of medical services in certain devices may not be realized because of the small scale of medical care providers (168). If small-scale providers are not organized to share services, then the full benefits of the device cannot be realized by potential users, and the device is unlikely to succeed. Yet, if the potential cost savings are high enough, the availability of a new technology may, with some delay, actually bring about a change in the organization of the market that allows for its adoption (268).

Although it is difficult to sort out the many factors contributing to the emergence of newly integrated health care organizations, changing medical technology may be one cause.

The importance of the market in stimulating innovation is indicated by the fact that 60 to 90 percent of successful innovations across many fields have been developed in response to the perceived needs of the market or of users (437). Any factors affecting the size of the market for an innovation, such as changes in the prices of close substitutes, changes in the ability of potential users to pay, and regulatory constraints on use (263), are likely to affect the innovative process.

In medical care, the market is determined in large part by mechanisms of third-party reimbursement for care (see ch. 3 for more detail). Russell found that the rate of diffusion of some (but not all) of the medical device innovations that she studied increased with the onset of Medicare coverage (265). Recent work indicates that prospective payment approaches can have some retarding effects on the quantity of new medical devices adopted by hospitals (448). Thus, the payment procedures used by insurance companies and other third-party payers may have an important indirect effect on innovative activity in the medical devices industry.

Conditions Affecting the Innovator's Ability to Appropriate Benefits

The need for investment in research, development, and commercialization implies that a potential innovator must be able to expect a return that will make the investment worthwhile.[3] In addition to an evaluation of the potential market, the expected return will depend on the degree to which the innovators can expect to capture or appropriate these benefits in profits or perhaps even directly as users. The ability to appropriate benefits affects not only whether innovation results, but also what kind of organization or individual undertakes the innovative activity (445).

One influence on the ability to appropriate benefits is the market structure of the industry, which influences the rate of imitation and therefore the market share that an innovator can expect over time. The effect of market structure is controversial. Schumpeter and Galbraith postulated that industries with a few dominant firms would be able to appropriate more of the benefits of their inventions because they face less of a threat from imitation and would therefore be more innovative than highly competitive industries (274).

Other researchers have concluded that high barriers to entry in an industry, particularly in relation to the capital investment required to compete, encourage research and development (R&D) by the firms in the industry (66). Fellner has suggested that the effect of monopoly power on the innovative process may differ between product and process innovations (112). Firms in industries in which a few firms hold a substantial share of the total market would have less to gain from introducing cost-reducing process innovations than would firms in highly competitive industries, and firms in more competitive fields may have to innovate to keep pace with rivals. Kamien and Schwartz observed that the greatest degree of innovation occurs in a market structure where rivalry is greater than in monopoly but less than in perfect competition (178).

Empirical evidence testing this hypothesis in U.S. industry is conflicting. Greer and Rhoades found that the rate of process innovation (as measured by productivity growth) was actually higher in concentrated industries, but Scherer points out that this association could be the result of a bias in process innovations toward large-scale operations, which are most likely to predominate in concentrated industries (134,274). Romeo, on the other hand, found that firms in concentrated industries adopted numerically controlled machine tools (a process innovation) more slowly than firms in more competitive industries (261).

The ability to appropriate benefits from investment may also depend on the size and level of diversification of the innovating firm. Larger firms with greater diversification may be able to apply a process innovation across a variety of applications and may therefore be able to recoup investment costs more readily (230). Empirical studies relating to this hypothesis are inconclusive (274).

Despite the large number of companies in the medical devices field, especially small ones, concentration in the medical devices categories is similar to that in other manufacturing industries. There is some evidence, however, that merger activity in medical devices accelerated during the latter part of the 1970s (see ch. 2 for details).

Government policies can also affect the extent to which a developer captures the benefits of an innovation. The patent system is, of course, designed for that purpose, but its power is limited. It is easy to design around some areas of technology, such as electronic circuitry and computer software (142). Also, firms holding critical patents may refuse to license them, thus blocking further technological innovations (142). In short, the ability to appropriate benefits may carry with it the ability to resist pressure to apply potential innovations.

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[3] The innovator's best guess about the potential market may be wrong, for uncertainty and failures of human judgment are inherent in the process. Unless there is some reason to suspect a bias in the direction of error, however, the investment decision can be assumed to deal with the probability of error through its tradeoff of expected risk for return. Government policies such as regulation may increase the level of uncertainty about outcomes of the innovative effort and therefore increase the level of expected return required to justify an R&D investment (97).

Conditions Affecting the Availability of Resources

Several scholars have noted the increasing institutionalization of R&D in the post-war period (175,182). Although there is variation across industries and fields of technologies, organized R&D as opposed to individual efforts have become the predominant source of innovation in this country as well as others. This trend toward institutionalization stems at least partly from the complexity of technology and the increasing need for financial resources and trained manpower to bring forth innovations.

Two kinds of resources are needed for R&D: personnel and financial capital. The availability of a pool of adequately trained personnel capable of carrying on R&D should become more important to technological innovation as the technology base gains in complexity. This OTA report does not explore issues of personnel or the role of scientific and technical education as it relates to industrial innovation in general and to the medical devices industry.

Financial capital can take the form of government or philanthropic grants and contracts for R&D, funds generated internally by firms (e.g., undistributed profits), and debt or equity instruments (including venture capital arrangements). The flow of these funds depends on the expected return and risk inherent in specific R&D projects, which in turn depend on the market and the appropriability of benefits. Government policies also influence the flow of R&D funds and therefore the location of R&D activities and the ultimate innovations.

As discussed in this OTA report, Government R&D policies influence not only the kinds of projects that are initiated, but also the kinds of organizations in which R&D takes place. Taxation policy also affects the availability of different kinds of capital. Appendix G discusses the impact of taxation policy on R&D for medical devices.

Conditions Affecting the Availability of Technical and Entrepreneurial Know-How

Successful innovation requires the joining of technical and entrepreneurial expertise. Although these areas of expertise need not reside in a single individual, they must be integrated in an appropriate fashion. Are there conditions or environments that foster or inhibit the existence and productive use of these skills?

A great deal of research has been devoted to determining whether or not the size of the firm has any relationship to its ability to develop innovations successfully. The size of the organization can be important to innovation for several reasons. First, larger firms may be more able to marshal the technical resources needed to conduct R&D on complex subjects. Second, large firms may be able to appropriate the benefits of innovations more easily than small firms. Third, large firms may have greater access to capital to finance R&D than small firms.

Against these possible advantages of large firms is one major advantage held by small firms. Small firms may be less burdened by cumbersome organizational structures that could inhibit coordination and timely decisionmaking on innovation. The interplay of these factors has suggested to some that there may be a threshold size necessary to support the R&D that results in innovation (203,179). Moreover, this threshold size is likely to vary from industry to industry. Empirical studies of the innovative process do not suggest any systematic patterns of advantage for large firms. One recent study, which examined 635 product innovations marketed during the 1970s, found that small firms accounted for approximately 40 percent of these (124). Other work has found some advantage to size but, again, only up to some threshold (200).

In a recent study, The Futures Group examined over 8,000 innovations published in trade journals in 1982 (123).[4] The number of innovations per employee was 1.43 times higher in small firms (500 employees or less) than in large firms. Innovations were categorized by Standard Industrial Classification (SIC) code. Rates of innovation in five medical device codes are presented in table C-1. With the exception of SIC 3851 (ophthalmic goods), small firms were over twice as innovative relative to levels of employment as large firms in the medical device industries.

There is also evidence from a Louis Harris survey that "the introduction of new medical devices is just as common in small as it is in large plants" (197). About one-half of the establishments with 500 or more employees introduced a significant new medical device in the last decade, while just under half of the firms with fewer than 500 employees reported doing so. (Indeed, more than one-half of the very small firms, 1 to 9 employees, reported such an introduction.)

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[4] This study, like others that depend on a sample of published innovations, is subject to possible selection bias. The bias is most likely in the direction of overrepresentation of innovations by large firms and more significant innovations. Hence, findings showing smaller firms to be more innovative are probably strengthened by this bias.

Table C-1.—Rates of Innovation in Five SIC Code Medical Devices Categories[a]

Standard Industrial Classification (SIC) code[b]	Innovations in 1982		Industry employment in 1977[d] (thousands)		
	Small firm[c]	Large firm	Small firm	Large firm	Innovations per employee small firm : large firm
3693	10	17	5.9	25.0	2.49
3841	36	30	11.7	31.5	3.23
3842[e]	33	30	17.9	36.0	2.21
3843	2	0	7.1	9.2	NA[f]
3851	2	9	11.1	18.9	0.38
Total	83	86	53.7	120.6	2.17

[a] Innovations were published in 1982 trade journals.

[b] The five SIC codes are as follows: 1) SIC 3693 (X-ray and electromedical equipment), 2) SIC 3841 (surgical and medical instruments), 3) SIC 3842 (surgical appliances and supplies), 4) SIC 3843 (dental equipment and supplies), and 5) SIC 3851 (ophthalmic goods). See ch. 2 for more information.

[c] Small firms have fewer than 500 employees.

[d] Employment in 1977 is used because a lag in journal publication of 4.3 years between invention and innovation was found in a detailed analysis of 375 innovating firms.

[e] This analysis excludes four innovations in SIC 3842, because the innovating companies could not be found in published directories.

[f] NA indicates information not available.

SOURCE: The Futures Group, "Characterization of Innovations Introduced on the U.S. Market in 1982," contract report prepared for the U.S. Small Business Administration, contract No. SBA-6050-0A-82, Glastonbury, CT, March 1984.

On balance, it appears that in the medical device field as in industry in general, small firms play an important role in spurring innovation, but the evidence is limited by the lack of consistent or validated measures of innovation and of any standardized criteria for assessing the relative importance of innovations. In addition, there may be a great deal of variation among industries and types of technologies in the most appropriate setting for bringing forth innovations. Scherer concludes that the issue of small or large may be irrelevant when what is needed is a variety of environments capable of responding to technological opportunities wherever they arise (274).

Appendix D.—Patent Policy Regarding Medical Devices

Introduction

The U.S. patent system started with British-based colonial patent systems which continued after the American Revolution. It is derived from a specific provision in the Constitution (357):

> The Congress shall have the Power . . . to promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors, the exclusive . . . Right to their . . . Discoveries.

The Supreme Court has interpreted this clause in our Constitution to mean that (132):

> The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must promote the progress of . . . useful Arts. This is the standard expressed in the Constitution and it may not be ignored. And it is in this light that patent validity requires references to a standard written into the Constitution . . .

There are four types of property rights in information, or intellectual property—patents, trade secrets, trademarks, and copyrights. Patents give the right to exclude others from using inventive concepts during the life of the patent. Trade secrets, traditionally under State not Federal law, give the owner of a technical or commercial secret the right to prevent someone with access to the secret from disclosing it or using it for personal gain. But if the secret can be discovered independently or is discovered by legitimate means (e.g., from analysis of the product), there is no protection. Trademarks give merchants the right to restrict their use by others who might benefit from the exploitation of established products (e.g., Coca Cola®, Darvon®, SweetnLow®). Copyrights provide the right to exclude others from copying the form of a work of art or a writing, but do not prevent others from using the ideas expressed in the copyrighted work (347).

Lately, a property right called a "tangible research property" has emerged separate and distinct from patents, copyrights, trademarks, and trade secrets. For example, in March 1982, Stanford University developed a separate policy on tangible research property to protect Stanford's ownership of "tangible (or corporeal) items produced in the course of research projects." This policy covers such items as "biological materials, computer software, computer data bases, circuit diagrams, engineering drawings, integrated circuit chips, prototype devices and equipment, etc." (289).

There are four types of patents, one of which, the "utility" patent, applies to useful processes, machines, manufactured articles, or compositions of matter. "Design" patents protect ornamental designs. "Plant" patents apply to asexually reproduced plants other than tubers or a plant found in an uncultivated state. "Plant variety protection certificates" provide patent-like protection to sexually reproduced plants. Certificates are administered through the U.S. Department of Agriculture. Utility, design, and plant patents are administered through the Patent and Trademark Office in the U.S. Department of Commerce (347).

The law on utility patents is as follows (347):

- An invention, to be patentable, must be useful and must be a process, machine, manufactured good, or composition of matter.
- A patent can be granted only for an invention that, at the time of the claim: 1) was not known to others, and 2) was not so obvious that a person of ordinary skill in the art could have made the same invention.
- A patent can be granted only to the inventor(s).
- A patent gives the owner the right to exclude others from making, using, or selling the invention in the United States. (There are some important conflicts between the patent laws of the United States and those of other countries.)
- A patent is granted for 17 years.

About 100,000 patent applications are filed per year, of which about two-thirds are eventually granted. The average time from application to action is about 2 years. During this time, a patent examiner determines whether the invention is novel and not obvious (see above), primarily by searching files within the Patent and Trademark Office that contain information on U.S. and foreign patents and on literature such as professional journals (347).

Tables D-1 and D-2 summarize the number of patents granted by the U.S. Patent Office between 1970 and mid-1983. In table D-1, patents are enumerated by the date of the patent grant, while in table D-2, successful patent applications are listed by the dates when patent applications were first filed. The date when an application is filed is a more accurate reflection of when the technology was developed. Fluctuations in data based on application dates are more likely to reflect changes in technological activity, since such fluctuations would be unaffected by changes in the Patent and Trademark Office's processing of patent applications. For example, the 1979 patent grant data

Table D-1.—Patent Activity by Date of Patent Grant, U.S. and Foreign Origin, 1970-83

	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983
Total	64,429	78,317	74,810	74,143	76,278	72,002	70,226	65,269	66,102	48,854[a]	61,819	65,771	57,889	24,383[b]
U.S. origin	47,077	55,984	51,524	51,504	50,650	46,713	44,277	41,484	41,254	30,081	37,356	39,223	33,896	14,144
(Percent)	(73)	(71)	(69)	(69)	(66)	(65)	(63)	(64)	(62)	(62)	(60)	(60)	(59)	(58)
Foreign origin	17,352	22,333	23,286	22,639	25,628	25,289	25,949	23,785	24,848	18,773	24,463	26,548	23,993	10,239
(Percent)	(27)	(29)	(31)	(31)	(34)	(35)	(37)	(36)	(38)	(38)	(40)	(40)	(41)	(42)

[a] This number is artificially low because the Patent and Trademark Office issued fewer patents than normal because of a lack of funds to print patents.
[b] Includes data only to June 1983.

SOURCE: U.S. Department of Commerce, Patent and Trademark Office, Office of Technology Assessment and Forecast, "OTAF Custom Report, All Technologies Report, 1/1963-6/1983" (mimeo), 1983.

Table D-2.—Patent Activity by Date of Patent Application, U.S. and Foreign Origin, 1970-83

	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983
Total	65,942	66,353	63,356	66,278	66,381	65,807	65,695	65,697	64,931	64,081	58,228[a]	23,816[a]	1,647[a]	1[a,b]
U.S. origin	45,851	45,580	42,429	42,733	41,830	42,198	41,566	40,652	39,222	37,978	34,403	14,765	1,150	0
(Percent)	(70)	(69)	(67)	(64)	(63)	(64)	(63)	(62)	(60)	(59)	(59)	(62)	(70)	(0)
Foreign origin	20,091	20,773	20,927	23,545	24,551	23,609	24,129	25,045	25,709	26,103	23,825	9,051	496	0
(Percent)	(30)	(31)	(33)	(36)	(37)	(36)	(37)	(38)	(40)	(41)	(41)	(38)	(30)	(100)

[a] Data incomplete because of lag time between application and approval.
[b] Includes data only to June 1983.

SOURCE: U.S. Department of Commerce, Patent and Trademark Office, Office of Technology Assessment and Forecast, "OTAF Custom Report, All Technologies Report, 1/1963-6/1983" (mimeo), 1983.

(see table D-1) are low, not because of a decrease in technological activity, but because the Patent Office issued fewer patents than normal because of a lack of funds to print patents.

Table D-2, summarizing successful patent applications by the date of patent application, shows that U.S. patents have remained at approximately 65,000 per year through the 1970s (data for 1980 and subsequent years are incomplete because of the delay between application and final ruling by the Patent and Trademark Office). During this period, patents of foreign origin increased from 30 to 40 percent of successful applications. About one-fourth of these patents of foreign origin were Japanese, closely followed by patents from West Germany (217).

Table D-3 summarizes 1981-83 data for selected indexes. In addition to the fact that about 40 percent of patents were of foreign origin, more than 75 percent were of corporate origin, about 2 percent were U.S. or foreign-government owned, and about 7 percent were owned by a foreign-resident inventor but assigned to a U.S. organization.

A patent can be sold (assigned), or it can be licensed on an exclusive or nonexclusive basis. An exclusive licensee has the right to enforce the patent. Nonexclusive licenses, granted to more than one party, are simply promises that licensees will not be sued for patent infringement. Payment for a license is usually by fee (e.g., $10,000 per year) or by royalty, based on some measure of income such as frequency of use of the invention or percent of sales of the invention (or products incorporating it).

Patent owners police their own patents. If they believe that their patents are being infringed, they may let unauthorized uses continue and try to collect licensing fees from the unauthorized users. But if the users refuse to cooperate, patent owners must go to court to obtain an injunction against the unauthorized use and to collect damages.

Table D-3.—Data on Patent Approvals, Selected Indexes, 1981–83[a]

Percent corporate-owned	76.87%
Percent government-owned	2.37%
Percent foreign-origin	41.06%
Percent U.S.-owned of foreign	7.17%

[a] Definitions: **Percent corporate-owned:** 1981-83 U.S. patents assigned to corporations/1981-83 patents x 100. **Percent government-owned:** 1981-83 U.S. patents assigned to the U.S. or foreign governments/1981-83 patents x 100. **Percent foreign-origin:** 1981-83 U.S. patents with foreign resident inventor/1981-83 patents x 100. **Percent U.S.-owned of foreign:** 1981-83 U.S. patents with a foreign resident inventor that are assigned to a U.S. organization/1981-83 patents with a foreign resident inventor x 100.

SOURCE: U.S. Department of Commerce, Patent and Trademark Office, Office of Technology Assessment and Forecast, "OTAF Custom Report, All Technologies Report, January 1963 to June 1983 (mimeo), 1983.

The U.S. patent system is currently undergoing major changes. In July 1981, reexamination proceedings were initiated under which anyone can request that a patent be reexamined (accompanied by a $1,500 fee). The Patent and Trademark Office can refuse to reexamine on the basis that no substantially new question was raised. In the same law (Public Law 96-517) that authorized reexamination (in which other parties can challenge a patent), Congress also required the Patent and Trademark Office to submit a plan to Congress by December 1982 on modernizing its files.

Patent protection is intended to stimulate invention by giving potential inventors the exclusive right to any benefits for a substantial time. A patent is also granted as a reward for the early disclosure of the invention to the public and not as a reward for either its discovery or for investment in its commercial development and exploitation. If the public would benefit eventually from the invention through its public disclosure or commercial use, no reward would be necessary and no patent would be given (101). This is the reason for the patenting requirements of novelty and not being obvious to someone working in the same field, and for the requirement that the patent application must contain enough information so that someone else can copy it.

Some International Aspects of Patents

Only some of the international aspects of patents are discussed here. One example of differences between the United States and other countries in the area of patent law is the concept of "prior art." In the United States, there is a 1-year grace period between publishing of the invention (e.g., of a new technique in a professional journal) and filing for a patent. Most universities routinely require researchers to report promptly inventions with potential commercialization so that the university can assess their potential and file for a patent. Most other countries do not have such a grace period.

Another example is that under current U.S. patent law, it is legal to import a product made in another country by a process covered by a U.S. patent without permission of the patent holder. A proposal to make this an infringement of the U.S. patent was reportedly part of the Patent and Trademark Office's 1983 legislative proposals (220).

Under the Paris Convention of 1883, patent holders are given a commercial monopoly (subject to certain conditions) for their inventions in 92 signatory countries. Patent holders must publish details of their discoveries in the signatory countries for other scientists to study, but the invention may not be copied for profit. Member countries may allow rival manufacturers to produce the invention if patent holders abuse their monopoly, for example, by neglecting to produce the invention in the affected countries.

The Paris Convention is administered by the United Nations' World Intellectual Property Organization. In the third conference on revisions of the Paris Convention for the Protection of Industrial Property, held in Geneva in October 1982, the main issue was a proposal that would make it easier for developing countries to confiscate and manufacture patented inventions.

Third-world governments had wanted a provision giving them the right to take over and manufacture on an exclusive basis any potential invention it the original patent holder did not produce it in their country within 30 months of receiving a patent. The intent was to force foreign manufacturers to produce their inventions in the developing country instead of producing them elsewhere and importing them. Third-world countries claimed that large companies that hold most patents can use imports to undercut a local manufacturer allowed to use their technology, so an exclusive license barring even the original patent holder was necessary for local production. The proposal would also have allowed a registered patent to be confiscated altogether after 5 years.

The developed countries opposed the proposal as an expropriation of private property and because large companies would become more secretive about their inventions and reluctant to invest in developing countries. Chemical and pharmaceutical companies were thought to be most vulnerable, because their patented products are relatively easy to make once their formulas are known.

Prior to the October 1982 conference, Japan and the West European countries had agreed to the proposal, arguing that developing countries would find a way to do it anyway, and that defining the conditions under which exclusive licenses were granted would give more, not less, protection. At the conference, the United States offered a compromise proposal that would grant nonexclusive licenses, but no agreement was reached (194).

Patents and New Product Development

The value of patents in the decision to undertake innovative activities depends on the type of invention and on the type of decisionmaker. For example, the pharmaceutical industry rarely pursues the development and regulatory approval processes for a new drug unless it can be patented. Also, recall that drugs and other chemicals, once identified, are relatively easy to copy. In the 97th Congress, extension of the patent term to recover time lost to the regulatory approval process was the Pharmaceutical Manufacturers Association's number one legislative priority, but it lost narrowly in the supplemental session of Congress. In contrast, much of the innovation in the electronics industry has occurred without patents.

The importance of patents to small businesses is also variable. Many small firms depend on trade secrets rather than on patents. Reasons include the expense of obtaining or having to defend patents, and the uncertain outcome if the patent is challenged (234).

But the smaller of the small firms usually consider patents to be more critical than do large businesses. There are anecdotes of the importance of patents in securing financial support. In interviews conducted for another OTA study (347), eight venture capitalists distinguished between two types of investments: 1) those that rely on a firm's management team and rapid advances in technology to provide protection from competition, with the emphasis on short-term payouts on the investments; and 2) technologies that require a long research and development period, for which patents become almost a prerequisite for investment.

In essence, the confidence that is placed in patents is a key to determining the incentives for innovation provided by patents. Little is statistically known about these factors, but it appears that the degree of confidence varies over a wide range.

For products that require large capital costs, such as automobile manufacturing, patents may have little bearing on investment decisions because of the limited ability of a competitor to enter the market. But patents have another use for both large and small firms—defensive use to prevent others from stopping the patent holder in proceeding with his or her invention. One example is in the development of the computed tomography (CT) scanner (258):

> Before CT, few X-ray companies bothered with patents, since all the X-ray companies recognized that no one company had a monopoly on the patents, each would have had to license from the other to stay in business—the result being "why bother with patents?" EMI, who was new to the X-ray business, heavily patented their CT designs, and by the end of the decade was requiring substantial royalties from all the CT suppliers. As a defensive measure, the X-ray companies substantially had to change their patent practices; for example, we [General Electric] went from having the part-time use of one patent attorney to having three full-time patent attorneys. This, I believe, was totally the result of EMI's changing the practice of an industry.

Patenting of Medical Devices

The U.S. Patent and Trademark Office classifies patents into 400 to 500 functional categories, and no specific category encompasses all medical devices. The Food and Drug Administration's (FDA) Office of Economic Analysis decided which categories should be considered medical devices, and further categorized these devices as either "low" or "high" technology, depending on how "sophisticated" the device was (390).

Table D-4 identifies which types of medical devices have been categorized by FDA's Office of Economic Analysis as low or high technology and their patent categories and subcategories as classified according to the Patent and Trademark Office. Figures 2 and 3 in chapter 5 summarize U.S. and foreign medical device patents for these low- and high-technology medical devices by application date for 1968 to 1979. Low technology patents increased in the early 1970s from about 800 per year to a peak during 1973 to 1974 of between 1,200 to 1,300 per year and remained at that general level for the rest of the 1970s. Patents for high-technology medical devices, on the other hand, continued to increase throughout the 1970s, doubling from more than 500 per year in 1970 to more than 1,000 per year by 1979.

In sum, in the 1970s: 1) there was a modest increase in the annual number of successful patents for medical devices, while there was essentially no increase in annual total patents granted; 2) patents for low-technology medical devices increased in the early 1970s but remained essentially constant for the rest of the decade, while patents for high-technology medical devices continued to increase throughout the decade; and 3) while the percent of foreign-origin patents increased for both medical devices and all inventions by approximately 10 percent, the percent of foreign-origin medical device patents (30 percent) was still lower than the percent for all patents (40 percent) by the end of the 1970s.

Table D-4.—High- and Low-Technology Medical Devices as Classified by FDA's Office of Economic Analysis

High-technology devices:

- A. Diagnostic equipment
  1. Cardiac devices (128) 695-715[a]
  2. Vascular devices (128) 669-694
  3. Respiratory devices (128) 716-730
  4. Stimulators, neurological, etc. (128) 731-746, 639-644
  5. Radiation (128) 653-667
  6. Other (128) 630-782, minus above codes plus 3-23
- B. Respiratory methods
  1. Mixing (128) 203.12-204.14
  2. Supply (128) 204.18-205.26 plus 207.14-207.18
  3. Substance removal (128) 205.27-207.13
  4. Other (128) 200.11-200.23 and 204.15-204.17
- C. Electrical systems and energy applicators (128) 419R-804
- D. Implantable artificial body members
  1. Cardiovascular (3) 1.4-1.7
  2. Legs, arms, bones, etc. (3) 1.913-2
  3. Other (3) 1-1.2 and 13-36
- E. Dialysis and blood filters (210) 321A-321B and (422) 44-48
- F. Miscellaneous (includes incubators, hearing aids, magnetic devices) (128) 1R-1.5 and (181) 126-137

Low-technology devices:

- A. Kinesitherapy (128) 24R-67
- B. Orthopedic (128) 68-80J, 81A-81R, 581-623
- C. Bandages and trusses (128) 82-171
- D. Medicators (604) 1-7, 11-19, 23-42, 46-72, 77-93, 104-170, 173-238, 239-263, 272-279, 285-302, 303-311, 403-416, 890-897
- E. Instruments (604) 8-10, 43-45, 94-103, 171-172, 264-271, 280-284
- F. Dental
  1. Orthodontics (433) 2-24
  2. Apparatus (433) 25-166
  3. Prosthodontics (433) 167-214
- G. Ophthalmic
  1. Examining equipment (351) 1-40
  2. Frames (351) 41-158
  3. Lenses (351) 159-177
- H. Miscellaneous (includes receptors, baths, canes) (604) 20-22, 73-76, 312-377, 378-402, (128) 362-403

[a] Numbers refer to categories (in parentheses) and subcategories according to the Manual of Classification, U.S. Department of Commerce, Patent and Trademark Office.

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, Rockville, MD, personal communication, December 1983.

Appendix E.—Method Used for OTA's Analysis of Applications to the National Institutes of Health for Small Business Innovation Research Grants

The data in table 31 (see ch. 4) are the result of an OTA analysis of the Small Business Innovation Research (SBIR) grant applications submitted to the National Institutes of Health (NIH) for funding in October 1983. OTA obtained copies of all applications submitted to NIH. A 50-percent-interval sample of applications (one of every two) was selected for analysis. (The total sample of 297 was selected from the 593 applications submitted.)

Using the Food and Drug Administration's definition of a medical device, OTA divided the NIH SBIR grant applications into three categories:

- biotechnology applications (includes medical device and other applications involving biotechnology),
- medical device applications (includes medical device applications not using biotechnology), and
- all other applications.

An application was categorized as a biotechnology application if the proposed research and development involved the use of recombinant DNA or other recently developed genetic, cell fusion, or bioprocessing techniques. An application was classified as a medical device application if, first, it did not use biotechnology and, second, it involved either research leading to the actual development of a medical device or research into techniques or products that would subsequently be used in the development of a medical device (i.e., the development of new materials for use in a medical device).

Because judgment was involved in categorizing the applications, inter-rater reliability was tested by having an independent rater analyze 36 randomly selected applications from the sample (approximately 10 percent of the sample). The two independent raters agreed on 26 out of the 36 applications (72 percent). This is significantly higher than the level that would be expected by chance, but nevertheless allows a substantial level of variation.

Appendix F.—The Database of Venture Economics, Inc., on Sources of Financial Capital

Venture Economics, Inc., the research and consulting division of Capital Publishing Corp., maintains an extensive database of information on the U.S. venture capital industry. The Venture Economics database currently tracks investments by the leading venture capital firms, both independent private and corporate groups, which account for more than 80 percent of the U.S. venture capital industry's total investment activity. In addition, the database covers the investment activities of Small Business Investment Corporations (SBICs) involved in classic venture capital type investments. The database does include a small degree of investment by foreign sources in U.S. companies as well as investment from unidentified sources, some of which may be non-venture-capital institutional funding.

Through extensive data collection efforts, Venture Economics has been able to research and computerize information on more than 4,300 companies that have received venture capital financing since the 1960s. Efforts to date have focused on the computerization of the following information on each portfolio company:

- company name and address,
- business description,
- industry or business codes including the Standard Industrial Classification code and more specific codes developed by Venture Economics,
- status of the firm (public or private),
- year founded, and
- for each round of financing:
  - — amount of financing,
  - — date of the financing round,
  - — stage of development of the company, and
  - — venture capital investors.

Table 30 in chapter 4, which listed the percentage of U.S. venture capital funds invested in medical imaging, other medical products, industrial products, and electronics, was based on the Venture Economics database's recorded venture capital investments for 1982. Although the investments recorded by the Venture Economics database do not account for all venture capital investments (see table F-1), in aggregate, they do offer a representative picture of venture capital investment activity. The categories of investors covered by the database are presented in table F-2. Medical imaging and the three other industry/product categories mentioned above, which were used in table 30 to classify firms receiving venture capital funds, are shown in table F-3. Definitions of the stages of financing used to categorize financing rounds in table 30 are shown in table F-4.

Table F-1.—Total Investments by the U.S. Venture Capital Industry, 1978-82 (millions of dollars)

Year	Total venture capital investments	Investments recorded by the Venture Economics database
1978	$ 550	$ 282
1979	1,000	500
1980	1,100	803
1981	1,400	1,400
1982	1,800	1,760

SOURCE: Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field," contract report prepared for the Office of Technology Assessment, August 1983.

Table F-2.—Categories of Investor Types Covered by the Venture Economics Database[a]

Independent private (225 investors):
Independent private funds
SBIC subsidiaries of private funds

Corporate financial (120 investors):
SBIC and non-SBIC subsidiaries of financial groups
Other investments by financial groups including insurance companies

Corporate industrial (125 investors):
Venture capital funds wholly or jointly funded by nonfinancial corporations
Direct corporate venture capital investors
SBIC subsidiaries of these industrial corporations

Nonaffiliated SBICs (140 investors):
Public and private SBICs not affiliated with any of the above investor types

Other (240 investors):[b]
Government affiliated groups
Community development corporations
Universities
Individuals
Foreign investors

[a] The number of investors in each category includes investment groups that are no longer active or that make only occasional investments.
[b] The majority of these are United Kingdom funds that do not invest in the United States on a regular basis.

SOURCE: Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field," contract report prepared for the Office of Technology Assessment, August 1983.

Table F-3.—Four Product Categories Used in the Venture Economics Database

Medical imaging:
- X-rays
- CT scanning
- Ultrasound imaging
- Nuclear imaging
- Other imaging

Medical products and services:
- Diagnostic (not including medical imaging):
  - Diagnostic services
  - Diagnostic test products and equipment
  - Other diagnostic
- Therapeutic:
  - Therapeutic services
  - Surgical instruments and equipment
  - Pacemakers and artificial organs
  - Drug delivery and other therapeutic equipment
  - Other therapeutic including defibrillators
- Other medical or health related:
  - Disposable products
  - Handicap aids
  - Monitoring equipment
  - Other medical or health related (not including pharmaceuticals, fine chemicals, or hospital and other institutional management including management services and leasing)

Industrial products:
- Advanced materials (including production processes)
- Industrial automation
- Industrial equipment and machinery
- Chemicals
- Pollution and recycling equipment
- Other industrial products

Other electronics industry segments:
- Electronic components:
  - Semiconductors
  - Microprocessors
  - Controllers
  - Circuit boards
  - Display panels
  - Other electronic components
- Batteries
- Power supplies
- Electronics-related equipment:
  - Semiconductor fabrication equipment and wafer products
  - Component testing equipment
  - Other electronics-related equipment
- Laser related
- Fiber optics
- Analytical and scientific instrumentation:
  - Chromatographs and related laboratory instrumentation (including spectrometers)
  - Other measuring devices (including infrared gas analyzers, moisture analyzers)
  - Other analytical and scientific instrumentation
- Other electronics-related equipment:
  - Military electronics (excluding communications)
  - Copiers
  - Calculators
  - Other electronics related

SOURCE: Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field," contract report prepared for the Office of Technology Assessment, August 1983.

Table F-4.—Definitions of Stages of Venture Capital Financing

Early stage:

Seed—A relatively small amount of capital provided to an inventor or entrepreneur to prove a concept. It may involve product development but rarely involves initial marketing.

Startup—Financing provided to companies for use in product development and initial marketing. Companies may be in the process of being organized or have been in business a short time (1 year or less), but have not sold their product commercially. Generally such firms would have assembled the key management, prepared a business plan, and made market studies.

First stage—Financing provided to companies that have expended their initial capital (often in developing a prototype) and require funds to initiate commercial manufacturing and sales.

Expansion:

Second stage—Working capital for the initial expansion of a company which is producing and shipping and has growing accounts receivable and inventories. Although the company has clearly made progress it may not yet be showing a profit.

Third stage—Funds provided for the major growth expansion of a company whose sales volume is increasing and which is breaking even or profitable. These funds are utilized for further plant expansion, marketing, and working capital or development of an improved product.

Fourth stage—The last round of private financing prior to, but not in anticipation of, a public offering or prior to the point at which a company can qualify for credit-oriented institutional term financings. This round may enable institutional term financing or may involve turnaround aspects.

Bridge financing—Financing for a company expecting to go public within 6 months to a year. Often bridge financing is so structured that it can be repaid from proceeds of a public underwriting. It can also involve restructuring of major stockholder positions through secondary transactions. This would be done if there were early investors who wanted to reduce or liquidate their positions, or if management had changed and the stockholdings of former management, their relatives and associates, were to be bought out to relieve potential overhead stock supply when public.

Leveraged buyouts and acquisition:

Acquisition for expansion—Funds provided to a firm to finance its acquisition of another company.

Management/leveraged buyout—Funds provided to enable operating management to acquire a product line or business (which may be at any stage of development) from either a public company or private company (often such companies are either closely held or family-owned). This usually involves revitalization of the operation, with entrepreneurial management acquiring a significant equity interest.

Other:

Turnaround—Financing provided to a company at a time of operational or financial difficulty with the intention of "turning around" or improving the company's performance.

Secondary purchase—Purchase of securities from another venture capital firm, other stockholders, or on the open market.

SOURCE: Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field," contract report prepared for the Office of Technology Assessment, August 1983.

Appendix G.—Tax Policy and Research and Development on Medical Devices[1]

Introduction

Much attention has been paid to potential effects of tax policy on incentives for innovation. Renewed interest in this question has recently been prompted by enactment of the Economic Recovery Tax Act of 1981 (ERTA) and the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). As a result of both ERTA and TEFRA, basic changes were made in both the personal and the corporate income tax including: 1) changes in marginal tax rates on personal income, 2) changes in the tax rules for depreciation of capital goods, and 3) enactment of new provisions applying to research and development (R&D).

Assessing the impact of these tax changes on the financial incentives for innovation generally, let alone innovation in medical devices, is extremely complex. However, it is possible to identify two distinct ways in which tax policy changes such as ERTA and TEFRA can affect incentives for innovation. First, tax incentives may alter the expected after-tax returns received by prospective purchasers of goods that embody innovations, thereby stimulating, or inducing, the demand for such innovations. Second, both personal and corporate income taxes will cause after-tax prices in capital markets to diverge from pre-tax prices. Both the size of this divergence and its pattern among different types of investments may influence the willingness of firms and individuals to invest in R&D and innovation.

Taxes and Induced Innovation

There is some evidence that the level of innovative activity in the development of particular goods is related to the overall level of demand for those goods. A particularly important example of such induced innovation is the case of capital goods innovation, where several empirical studies have shown that the level of capital spending by industry affects the level of innovation in capital goods (273, 276). Because ERTA/TEFRA permit firms to deduct the costs of depreciable assets more rapidly than was previously allowed, these tax policy changes are expected to stimulate greater capital spending by industry. According to the induced-innovation hypothesis, such increased capital spending should also stimulate innovative activity among those firms producing capital goods.

Many medical devices are clearly capital goods. However, the market for medical devices differs from the market for other capital goods in one important respect. Because many of the purchasers of medical devices are not subject to taxation, their demands for medical devices should not be directly affected by tax rules governing depreciation of capital goods. Thus, the tax provisions of ERTA/TEFRA may be expected to have a smaller impact on the capital spending decisions of purchasers of medical devices than of purchasers of other capital goods.

This situation implies that any induced innovation attributable to ERTA/TEFRA will also be less in the case of medical devices than other capital goods. Of course, TEFRA contained a section specific to Medicare payment of hospitals, which, with its subsequent modifications under the Social Security Amendments of 1983 (Public Law 98-21), dramatically altered the incentives of hospitals to purchase medical technology (see ch. 3 for details).

Another, perhaps more important, way in which the tax code can affect the demand for medical devices is through the tax treatment of employer-paid health benefits. Because such benefits are typically treated as nontaxable fringe benefits, employees, particularly those facing high marginal tax rates, have a tax incentive to receive part of their labor compensation in the form of such benefits. The growth of health benefit plans has been one of a number of factors contributing to growth in demand for health services during the postwar period, and this growth in demand may also have encouraged innovations in medical devices.

Although the tax-exempt status of fringe benefits has not been affected by ERTA/TEFRA, there has been some support for changes in tax law which would limit the tax exemption currently enjoyed by all fringe benefits, included employer-paid health benefits. If these changes were enacted, it is likely that both the level and composition of demand for health services would be affected, and this change in turn could have some impact on the level and type of R&D in the medical devices industry.

Taxes and Suppliers of Innovation

The ultimate suppliers of innovations are the individuals or firms who choose to allocate resources to R&D rather than to other investment projects. In part, such choices are made outside the boundaries of the firm in external capital markets by individual investors who must decide how to allocate their portfolios of wealth among different investments. In part, such choices are made within the firms by managers who must choose among competing uses of a firm's capital budget. In both cases, however, the tax treatment of different investment options is an important factor in the ultimate investment decision.

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[1] This appendix was written for OTA by Barth and Cordes (27).

Two alternative investments may be equally productive before the income from such investments is taxed and yet earn different after-tax returns if one investment is taxed relatively more heavily than the other. In such an event, two investments which are equally attractive insofar as social returns are concerned are not equal in the eye of the prospective investor, who will choose the investment with the higher after-tax return.

In the case of R&D investments, there are two principal ways in which the tax code affects their after-tax return compared to other investment activities. The first is the tax treatment of capital gains. The second is the tax treatment of inputs specific to the innovation process.

Taxation of Capital Gains

The expected returns on an investment may be realized through annual flows of income, through capital gains or losses resulting from changes in the asset price of the investment, or through some combination of annual flows and changes in asset values. In the absence of taxation, the manner in which the return was expected to be received would be irrelevant to the ultimate investment decision. All that would matter would be the total expected return (annual expected flows plus or minus capital gains and losses) and the expected risk (the variance of realized returns around the total expected return). However, because capital gains and capital losses are treated differently from income under U.S. income tax, investments whose returns are realized primarily through capital gains or capital losses will be evaluated on a different after-tax basis from investments whose returns are realized through annual flows of ordinary income.

At present, capital gains are not taxed until they are actually realized into cash through sale of the asset. More importantly, if the asset is held for longer than 1 year, the capital gain that is realized is taxed at a rate which is generally 40 percent of the tax rate applied to ordinary income. Thus, for example, if a person's tax rate on ordinary income were the maximum rate of 50 percent, the tax rate applied to each dollar of long-term capital gain would be 20 percent. If the investment should prove unsuccessful, and a capital loss is realized, the loss may be offset dollar for dollar against capital gains. However, if reported capital losses are greater than the capital gains, the net capital loss may be only partially applied as a deduction against ordinary income.

In effect, the U.S. tax system provides preferential treatment to investments which pay off in the form of capital gains, while providing less than complete tax offsets to investments which result in capital losses. Assessing the impact of such a system on the propensity of investors to take risk—and by implication to invest in innovative activities—is an extremely complex task, and the conclusions that emerge from such an assessment depend on the standard used for comparison.

If the alternative is a tax system which taxed capital gains in full but also allowed full and complete deductibility of capital losses, it would be impossible to ascertain on theoretical grounds which of the two tax regimes—the current one, or the alternative—is the most favorable to risk-taking because the differences would work in opposite directions. However, compared with an alternative system which taxed capital gains the same as ordinary income but continued to allow only partial tax offsets for capital losses, preferential tax treatment of capital gains encourages more risk-taking. That is, given that loss offsets are incomplete, partial rather than full taxation of capital gains may be one way of preserving incentives for risk-taking.

Two groups of individuals for whom the tax treatment of capital gains would appear to be particularly important are the entrepreneur-founders of new ventures and the venture capitalists who provide external financing to such ventures. Those who choose to become entrepreneurs have in effect chosen to forgo relatively certain returns to their human capital (i.e., labor) which could be earned from salaried employment, as well as returns to any personal financial capital they invest, in order to develop an idea or invention into a new product or service.

Presumably, this decision is motivated by a variety of considerations and is certainly not limited to tax factors. However, the fact that the expected returns to entrepreneurship will typically be realized in the form of increases in the value of the entrepreneur's ownership share in the firm, which in turn will be taxed favorably as capital gains, would at the margin encourage rather than discourage entrepreneurship. Indeed, there is some empirical evidence that the preferential tax treatment of capital gains has influenced the decision of individuals between salaried employment and entrepreneurship (151).

Similar considerations apply to individual venture capitalists. Although such persons are not themselves actively engaged in the development of innovations, they typically share in both the risks and rewards of entrepreneurship through equity participation in the entrepreneurial firm. The fact that any returns to such participation are likely to be realized through appreciation in stock values, and therefore to be taxed favorably as capital gains, would, at the margin, encourage the commitment of venture capital.

Data provided to OTA on the organized venture capital market suggest that venture capitalists are more likely to commit funds to the early stages of firm development in the case of medically oriented ventures than they are in the case of other industrial ventures (see table 30 in ch. 4). The data also show that capital provided to medical device ventures is more likely to come from private, independent sources than from corporations or small business investment companies (443). These two considerations imply that *individual* tax incentives which encourage the commitment of risk capital may be of special importance to innovation in medical devices.

Finally, the current tax treatment of capital gains interacts with the double-taxation of dividends at the corporate level to encourage earnings retention rather than dividend payout. If earnings are paid out in dividends, such income will be taxed in full at ordinary income tax rates. However, if the earnings are retained and reinvested, stockholders can defer paying personal taxes until any expected capital gains are realized through sale of stock, and then do so at preferential capital gains tax rates. As a result, the effective tax on income from corporate equity is less under earnings retention than under dividend payout. At the margin, this encourages firms to retain earnings and, if retained earnings are an important source of funds for some innovations, enhances the financial resources available for innovative activities.

The current tax treatment of capital gains would appear to provide benefits to investments in medical device innovations which are equal to those provided to other risky investments. However, the overall value of the tax preference on capital gains to the highest income investors has been somewhat reduced by ERTA, which lowered the maximum tax rate on "unearned income" from 70 to 50 percent.

Corporate Tax Policy

In the case of relatively established firms, the decision to engage in R&D requires that resources be used to develop and produce a new product which could instead be used to enhance the firm's ability to produce its existing products. If the firm's ultimate objective is to maximize its value, this implies that capital should be allocated to R&D up to the point where the last dollar allocated earns a risk-adjusted expected after-tax return equal to that earned from a dollar invested in a more traditional investment activity.

If the tax code is neutral in its treatment of the productive inputs used in different investment projects, tax considerations will not influence the firm's allocation of capital among competing investment activities. However, if the tax code favors the use of certain inputs, and if these favored inputs are specific to certain types of investment projects, tax considerations will affect the amount of capital allocated to different projects. In effect, investments that use tax-favored inputs will be encouraged, because they will need to earn a lower pre-tax return in order to earn a given after-tax return than will investments that do not use tax-favored inputs.

Tax Treatment Before and After ERTA/TEFRA.—In the case of R&D, the issue is whether the inputs used for R&D are treated more or less favorably than inputs used in other investment activities. The two principal inputs needed to develop innovations are tangible capital in the form of depreciable assets and intangible capital arising from expenditures on R&D.

Prior to the enactment of ERTA/TEFRA, tangible capital used in conducting R&D was treated the same as tangible capital used for other purposes. Firms using such capital were entitled to claim an investment tax credit on new equipment, but not structures, and could then claim a stream of depreciation deductions over a number of years based on guidelines established by the Department of Treasury. However, neither the amount of the investment credit nor the speed at which the asset could be depreciated were related to the type of investment project in which the asset was used—i.e., to whether the asset was used in R&D or in a more traditional investment activity.

Other costs of R&D were, however, given special treatment. Specifically, section 174 of the Internal Revenue Service Code allowed the salaries and expenses incurred to develop R&D to be deducted immediately in the year incurred. This "expensing" of R&D was viewed as preferential treatment because R&D salaries and expenses were seen as part of the costs of acquiring an intangible asset which was capable of providing services to the firm over a number of years. Under this view, expensing confers favorable tax treatment on R&D activities.

Enactment of ERTA/TEFRA has altered the relative position of different kinds of investments in three ways. First, though the rules governing R&D expensing were not changed by ERTA/TEFRA, the rules governing depreciation of other capital assets have been liberalized considerably by adoption of the Accelerated Cost Recovery System (ACRS). Second, for the first time, tax depreciation rules treat equipment used in R&D as different from equipment used in other activities. Third, for the first time, R&D outlays which qualify for expensing may also qualify for a tax credit. In the remainder of this section, we examine how these measures—both singly and in combination—affect the relative attractiveness of innovative investments generally, and innovation in medical devices specifically.

Accelerated cost recovery. ACRS, enacted as part of ERTA with some modifications in TEFRA, speeds up the rate at which the costs of using depreciable assets may be recovered.

Depreciable capital assets (e.g., equipment and buildings) are important inputs into R&D. However, the capital intensity of R&D differs among projects so that the impact of changes in cost recovery rules will be greater for some types of R&D projects than for others. Liberalized cost recovery favors R&D projects that are relatively capital-intensive.

Detailed data on the capital intensity of R&D in different industries do not exist. However, National Science Foundation (NSF) data can be used to construct a crude index of factor intensity in R&D: the ratio of R&D expenditures to scientists and engineers employed in R&D. Other things being equal, this ratio should be higher in industries in which R&D is more capital-intensive. Based on this ratio, one may therefore ascertain whether R&D activities in any given industry benefit relatively more or less from ACRS.

While NSF data do not permit the above ratio to be calculated specifically for medical device producers, the ratio can be calculated for producers of optical, surgical, and photographic equipment (Standard Industrial Classification (SIC) codes 383-387). Between 1976 and 1979, the R&D capital-intensity ratio for this industry group exceeded the average ratio for all manufacturing industries. This suggests that the R&D investments of medical device producers in these SIC codes benefit relatively more from ACRS than do R&D investments of other manufacturers.

The overall effect of the ACRS on R&D in medical devices is unclear, however, because ACRS moves the tax treatment of non-R&D capital closer to that of R&D expensing. This reduces the relative attractiveness of using business funds for R&D expenditures that qualify for expensing. While ACRS has a scale effect favorable to all investment projects using depreciable capital, it has a substitution effect which tends to favor capital investments that do not involve R&D (27). That is, while ACRS reduces effective tax rates on all investments, it reduces them more for investment projects which are relatively less intensive in the type of R&D which qualifies for expensing. The net effect of the two effects on R&D in medical devices is unknown.

Special treatment of R&D equipment. One provision of ACRS which applies specifically to depreciable assets used in R&D is the assignment of all R&D equipment to the "3-year recovery class." Because of this provision, all equipment used in R&D must be depreciated over 3 years, even though the ACRS guidelines would normally require that the same equipment be depreciated over a longer period of time if used for other purposes. Because non-R&D equipment is assigned to either the 5- or 10-year recovery class, this provision would appear to favor R&D by allowing the capital costs of equipment to be deducted more rapidly if the equipment is used for R&D rather than in other activities. However, while equipment used in R&D may be written off more rapidly, all equipment in the 3-year recovery class qualifies for a smaller investment tax credit—6 percent—than equipment in the longer lived asset classes, which is eligible for a 10-percent investment credit.

Under ERTA, the disadvantage of receiving a smaller investment credit was large enough to offset the advantage of more rapid writeoff. However, because of changes made in TEFRA which reduced the value of the writeoff, this no longer appears to be the case. Given the current set of tax rules, the net effect of grouping R&D equipment into a special recovery class is favorable to equipment used in R&D. (For a more elaborate discussion, see Barth, Cordes, and Tassey, 1984 (27); Collins, 1983 (65); Zakupowsky and Sunley, 1982 (466).)

Tax credit for incremental R&D. As a result of ERTA, firms can also claim a tax credit for certain R&D spending. The amount of the credit equals 25 percent of the amount of which "qualified research expenses" during a year exceed the base period level of such expenses. The base period level is the average qualified expenses of the 3 preceding years, while qualified expenses are those defined in keeping with section 174 (the R&D expensing provision). If the firm pays other parties to conduct R&D, 65 percent of such purchases are deemed to be qualified research expenses. The R&D credit is scheduled to expire as of January 1, 1986.

Predicting the impact of the existing R&D tax credit is difficult for two reasons. First, the R&D credit is temporary rather than permanent. Second, the amount of the credit is based on incremental rather than total expenditures. A detailed analysis of the effect of the R&D credit is beyond the scope of this discussion (see Barth, Cordes, and Tassey, 1984 (27) for a complete treatment), but it is possible to make a rough assessment of the benefits which producers of medical devices have thus far derived from the R&D credit in relation to firms in other industries.

In a preliminary sample of 1981 tax returns taken by the Department of Treasury, producers of optical, medical, and ophthalmic goods claimed R&D credits equal to 5.4 percent of total eligible R&D spending, while the corresponding figure for producers of other electrical equipment, including manufacturers of electronic medical devices, was approximately 3.5 percent (418). These percentages may be compared with the percentage for all of the manufacturing firms sampled, which was 4.8 percent.

Results reported by Eisner and colleagues for 1981, based on data in the Compustat tapes, are qualitatively consistent with these estimates. Specifically, Eisner and colleagues calculate that firms in the NSF industry group "optical, surgical, and other instruments" claimed R&D tax credits equal to 4.6 percent of eligible R&D, as compared with all manufacturing firms, which claimed R&D credits equal to 3.3 percent of eligible R&D (98a). However, their predictions for 1982 based on simulations indicate that producers of optical, surgical, and other instruments would be eligible to claim R&D credits equal to only 2.6 percent of qualifying R&D, as compared with all manufacturing firms, which would be able to claim credits equal to 2.8 percent of eligible R&D spending.

The differences reflect differences among the sampled firms in the rate of growth in eligible R&D. However, because the numbers pertain only to eligible R&D, they provide but a partial view of the relative impact of the R&D credit. The reason is that total R&D spending consists both of outlays for eligible R&D and outlays for R&D depreciable capital. Unfortunately, because R&D depreciable capital does not qualify for special tax treatment, firms are not required to report this component of R&D in their tax returns. Hence, it is difficult to estimate precisely the amount of R&D claimed as a percent of all R&D.

A crude estimate of this latter magnitude may be obtained as follows. In the case of all manufacturing firms, it has been estimated that total company R&D spending equals roughly 2 percent of sales (423). However, the total amount of eligible company R&D reported by manufacturing firms in the Treasury sample equals only about 0.66 percent of the receipts reported by the firms (418). This figure suggests that eligible R&D spending equals roughly 33 percent of all R&D spending by firms in the sample. In this case, the amount of R&D credits claimed as a percentage of *all R&D spending* would be 1.6 percent (one-third of 4.8 percent).

By comparison, NSF estimates that producers of optical, medical, and surgical instruments that perform R&D spend amounts on R&D which equal roughly 5 percent of sales (423). The total amount of eligible R&D reported by sampled producers of optical, medical, and ophthalmic goods equaled 0.8 percent of reported receipts. Thus, eligible R&D equaled roughly 16 percent of all R&D spending by this group of firms, so that the amount of R&D credits claimed as a percentage of all R&D would be 0.9 percent. With the same procedure it is estimated that producers of other electrical equipment (including medical electronic devices) claimed credits equal to 0.5 percent of total eligible R&D.

Thus, as a percentage total of R&D spending, the amount of R&D credit claimed by medical device producers may be less than that claimed by all manufacturing firms. Of course, the industry classifications make it difficult to generalize about medical devices per se. The difference arises because eligible R&D may be a smaller share of total R&D among medical device producers than it is among all manufacturing firms.

Conclusion

The analysis above suggests that the current tax system is generally favorable to R&D investments, but the incentives differ both among different types of innovation and among different phases of the innovation process. With respect to medical devices, the limited data available suggest that R&D is relatively capital-intensive. Consequently, medical device R&D should benefit somewhat more than other industries' R&D from the recent liberalization of tax depreciation allowances. However, to the extent that the innovative process in medical devices is more capital-intensive, the incentive effects of the incremental tax credit for R&D may be somewhat less for medical device producers than it is for firms whose R&D is more labor-intensive, because the special tax treatment of R&D does not apply to capital expenditures.

Appendix H.—Consensus Standards Related to International Trade in Medical Devices[1]

Introduction

The ability to market medical devices effectively outside the United States depends partly on regulatory controls imposed by the U.S. and foreign governments and on standards or specifications set by local, national, and international bodies. Most nations, including the United States, use regulations and product standards to control the sale of medical devices, both foreign and domestic. Although the need to protect public health and safety provides justification for governmental regulation, governmentally imposed requirements relating to standards, certifications, inspections and testing may create nontariff trade barriers.

Standards based on one nation's technology may by definition exclude foreign products. Testing and approval procedures, developed and required for domestic use, may be conducted in such a way as to inordinately increase importers' expenses. The internal orientation of certification systems may serve to limit access for imports or deny certification to imported products (379). These factors underscore the importance of international cooperation and coordination in standards-related activities.

The General Agreement on Tariffs and Trade (GATT) is the principal multilateral instrument that sets agreed rules for international trade. Its basic aim is to liberalize world trading practices through reduction of tariff and nontariff trade barriers. GATT, concluded in 1948 and currently subscribed to by 87 nations, provides a continuing forum for multilateral discussions and negotiations on trade matters. In contrast to earlier rounds of negotiations which focused almost exclusively on tariff issues, the "Tokyo Round," completed in 1979, focused on reducing or removing nontariff barriers to trade and resulted in six major agreements dealing with nontariff matters. One such agreement—The Agreement on Technical Barriers to Trade (or "Standards Code")—is of particular importance to the medical devices industry and currently has more signatories than any other GATT code (see table H-1). The Standards Code establishes international principles governing the development, adoption, or application of any standard or certification system by the signatories and thereby seeks to eliminate the use of standards and certification systems as nontariff trade barriers (379). Title IV of the Trade Agreements Act of 1979 (19 U.S.C. § 2501 et seq.) approved U.S. acceptance of the Standards Code and served to implement the code in the United States.

This appendix explores how established international trade agreements (such as GATT) and Federal laws (such as the Trade Agreements Act) have affected trade in medical devices, specifically as they relate to the development and application of standards. This appendix also describes organizations and agencies involved in medical device standards-setting procedures, their procedures, the effect of implementing their standards, and U.S. Government responsibilities in standards-setting.

Standards-Setting Organizations

U.S. Voluntary Consensus Organizations

Standards for medical devices in the United States have traditionally been developed in the private sector by professional organizations, trade associations, and voluntary standards organizations. These voluntary consensus standards are nonbinding standards developed by consensus among voluntary participants such as consumers, manufacturers, professional association representatives, physicians, clinical technicians, hospitals, and other users (117). Besides the organizations described below, additional ones represent specific interest groups such as hospitals, hospital sup-

Table H-1.—Signatories to the Standards Code[a]

Argentina
Austria
Belgium[b]
Brazil
Canada
Chile
Czechoslovakia
Denmark[b]
Egypt
European Economic Community[b]
Finland
France[b]
Federal Republic of Germany[b]
Greece[b]
Hungary
India
Ireland[b]
Italy[b]
Japan
Korea
Luxembourg[b]
Netherlands[b]
New Zealand
Norway
Pakistan
Philippines
Romania
Rwanda
Singapore
Spain
Sweden
Switzerland
Tunisia
United Kingdom[b]
Hong Kong
United States
Yugoslavia

[a] As of Nov. 1, 1983.
[b] The Standards Code is adhered to by the European Economic Community, in addition to being adhered to by the 10 member states of the community.

SOURCE: U.S. Executive Office of the President, Office of the U.S. Trade Representative, "Status of Tokyo Round MTN Agreement Signatures and Acceptances," Nov. 1, 1983.

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[1] This appendix was drawn from a paper prepared for OTA by Lepon and Gawron (193).

pliers, health industry manufacturers, mechanical engineers, dentists, and pathologists (see table H-2). Some of these organizations develop standards for use by their own membership or have representatives on the boards and committees of other standards-setting organizations.

American National Standards Institute, Inc. (ANSI).—ANSI is a private, nonprofit federation of standards-developing organizations and standards users. Founded in 1918, ANSI has been established over the years as the primary U.S. organization for sanctioning and approving voluntary standards in many fields. ANSI approves the American National Standards, a compilation of standards widely accepted by manufacturers, product purchasers, and other professional organizations. ANSI has delegated the planning and coordination of standards in the medical device field to its Medical Devices Standards Management Board, which is composed of representatives from professional societies, trade associations, Government agencies, and general interest groups.

Through this board, ANSI has approved nearly 200 standards for medical devices, primarily by accrediting the standards developed by other organizations. These standards include many for devices used for cardiovascular surgery, neurosurgery, ophthalmology, orthopedics, dentistry, anesthesiology, thoracic surgery, respiratory assistance, and in vitro diagnostic products. ANSI also represents the United States in international standards-setting bodies, most notably the International Electrotechnical Commission (IEC).

ANSI coordinates standards to eliminate duplication among those developed by different organizations. In addition, it serves as a clearinghouse to provide standards developers with information on the procedures and activities of other standards developers.

Before a standard can receive the American National Standards designation, it must be reviewed by ANSI's appropriate committees. To this end, ANSI solicits comments from interested parties on the proposed standard in an effort to ensure that its due process requirements are met. If, as is sometimes the case, other recognized national standards already exist, ANSI will work to harmonize the standards so as to eliminate any overlap in content and ensure that a voluntary consensus can be achieved among the affected organizations.

Association for the Advancement of Medical Instrumentation (AAMI).—AAMI is a nonprofit, professional association formed in 1967 and comprised of individuals, hospitals, health care facilities, professional and medical societies, Government agencies, manufacturers, and research and educational institutions concerned with the development, evaluation, and application of medical devices. Approximately 40 medical device standards, process guidelines, and recommended practices concerning such areas as critical care instrumentation are currently under development, and 11 are available in final form. AAMI carries out its work through technical committees composed of both medical device manufacturers and medical device users in an attempt to balance representation by the groups which will potentially be affected by any approved standards.

AAMI participates in the international standards-setting activities of organizations like the International Organization for Standardization (ISO) and IEC through its membership in ANSI. At the request of ISO and IEC, AAMI has placed its members on their technical committees. For instance, an AAMI participant sits on ISO's technical subcommittee for cardiovascular implants and represents the view of AAMI members.

American Society for Testing and Materials (ASTM).—ASTM, founded in 1898, is a nonprofit, nongovernmental organization involved in developing voluntary consensus standards. In medical devices, its standards primarily, but not exclusively, relate to materials used to manufacture devices. ASTM has over 30,000 individual members representing Government agencies, private physicians, hospitals, public and private laboratories, and medical device manufacturers. ASTM standards provide guidance in determining the biocompatibility of materials; define the properties and char-

Table H-2.—Additional U.S. Organizations Involved in Voluntary Standards Setting for Medical Devices

American Academy of Allergy
American Association for Clinical Chemistry
American Association of Blood Banks
American Association of Immunologists
American Dental Association
American Heart Association
American Hospital Association
American Institute for Ultrasound in Medicine
American Psychiatric Association
American Society for Artificial Internal Organs, Inc.
American Society for Microbiology
American Society of Mechanical Engineers
American Thoracic Society
College of American Pathologists
Compressed Gas Association
Health Industry Manufacturers Association
Hearing Industries Association
Illuminating Engineering Society
Institute of Electrical and Electronics Engineers
National Council on Radiation Protection and Measurements
National Electrical Manufacturers Association
National Sanitation Foundation
Pharmaceutical Manufacturers Association
Scientific Apparatus Makers Association

SOURCE: J. Lepon and E. Gawron, Kornmeier, McCarthy, Lepon, and Harris, "Medical Device Standards and International Trade," contract report prepared for the Office of Technology Assessment, 1983.

acteristics of such materials as plastics, metals, and ceramics; and establish testing methods and recommended handling practices for medical and surgical instruments. Nearly 30 technical committees are involved in reviewing and developing standards for medical surgical materials and devices.

National Fire Protection Association (NFPA).—NFPA is an independent, voluntary, nonprofit organization established in 1896 to protect people and their environment from destructive fires. NFPA's membership is comprised of interested individuals and representatives of national trade and professional organizations. A primary function is the development of safety standards and codes that eventually become part of the National Fire Codes, a multivolume set of final, approved NFPA standards.

In 1975, NFPA established a health care section to assist in the development of standards that may help to prevent fires in medical facilities. NFPA also encourages safe use of medical devices, particularly electrically powered medical devices, in patient areas. It participates in many other standards-setting organizations by placing its members or organizational staff on their technical committees. For instance, NFPA is an active participant on ASTM's committee on the hazard potential of chemicals and ASTM's subcommittee on flammability and ignition testing, AAMI's subcommittees on electrical safety and monitoring devices, and the U.S. Veterans Administration (VA) Advisory Committee on structural safety of VA facilities. Through its membership in ANSI, NFPA also assists in the review and development of the American National Standards and participates in the international standards development activities of IEC.

NFPA standards for safety have been widely accepted by States and local governments in establishing regulations for licensing of medical facilities and for regular building inspections. Although NFPA standards are voluntary, their adoption by the regulatory agencies of State and local governments have made some of them mandatory.

National Committee on Clinical Laboratory Standards (NCCLS).—NCCLS is a private, nonprofit corporation devoted to upgrading health care by improving the quality of clinical laboratory methods and by providing acceptable guidelines and standards for clinical laboratories. NCCLS was founded in 1968 by representatives of the clinical laboratory services professions, the Federal and State Government agencies with responsibilities for public health, and diagnostic products companies that provide the reagents, instruments, and systems used in clinical laboratory identification and measurement. Its members work to produce voluntary consensus standards through numerous technical committees.

NCCLS coordinates the process by which national consensus on clinical laboratory standards is achieved, and thus expedites the process by which NCCLS standards become adopted as national and international standards. It works closely with its European counterpart, the European Committee on Clinical Laboratory Standards, as well as with the International Organization of Legal Metrology, and ISO in developing and harmonizing international standards.

Underwriters Laboratories, Inc. (UL)—UL is an independent not-for-profit corporation established in 1894 to help reduce or prevent bodily injury, loss of life, and property damage. UL has developed standards and requirements covering medical and dental equipment intended for professional use by personnel in hospitals, nursing homes, medical care centers, medical and dental offices, and other health care facilities.

UL's standards for safety are based on research and cooperation by engineers, manufacturers, consumers, and recognized specialists in many fields. Many UL standards for safety are recognized as American National Standards by ANSI. UL is a member of ANSI and assists in the review and development of American National Standards. Its staff members serve on technical committees and subcommittees of various domestic standards developing organizations such as ASTM and NFPA, as well as international organizations such as IEC and ISO.

UL standards and requirements are the basis on which UL's registered certification mark may be affixed to complying products by subscribers to UL's services. This system of marking is recognized by consumers, regulatory authorities, and others who seek and rely on third-party certification of products with respect to safety. Federal, State, and municipal authorities, architects, building owners, and consumers may require listing or classification by UL as a condition of their acceptance of a device, system, or material having a bearing upon risk of fire, shock, or other injury to persons or property. Although UL standards for safety are voluntary, adoption by regulatory agencies has made some of them mandatory (109).

International Organizations

International Organization for Standardization (ISO).—ISO, formed in 1947, is an organization of national standards institutes involving over 84 countries. Its objective is to promote development of worldwide standards for the purpose of "facilitating international exchange of goods and services and to develop mutual cooperation in intellectual, scientific, technological, and economic ability" (169).

ISO recognizes ANSI as the representative member body for the United States. Other U.S. standards-setting organizations, including various Federal Government agencies and representatives of manufacturers, participate in many of ISO's technical committees that are concerned with medical devices. These groups together comprise the U.S. delegation to the international organization. Members participate on such technical committees as dentistry, implants for surgery, mechanical contraceptives, prosthetics, and transfusion equipment.

The development of international standards, of which there are nearly 200 relating to medical devices, is a slow, deliberative process. First, draft proposals are submitted by interested national standards organizations or individuals to technical committees for study. Most of the work of reviewing these proposals is done through correspondence with its members. The process of approving a standard may take as long as 6 or 7 years, but most proposed standards take about 3 years to gain approval as an International Standard.

Once a standard has become an International Standard, many national standards institutes and governments often seek to adopt it as their national standard as well. For example, ANSI, working through its American Dental Association members, has adopted the ISO standard for dental zinc silico-phosphate as an ANSI standard (ANSI/ADA 21-1981). The reverse case has also occurred, in which a specific national or regional standard has become an International Standard. This situation is becoming more common as many aggressive national and regional standards organizations attempt to have their own standards accepted internationally. For example, AAMI has introduced its draft standard for implantable ventricular pacemakers (AAMI IP) to ISO, which in turn accepted it as a draft International Standard (ISO 5841.1).

International Electrotechnical Commission (IEC).—IEC was formed in 1906. In accordance with a formal agreement between IEC and ISO, questions related to international standardization in the electrical and electronic engineering fields are reserved to IEC and other subject areas are the responsibility of ISO. If ISO undertakes an international standardization matter unrelated to a particular technology, it consults IEC to safeguard any electrotechnical interests that may be involved.

The structure and process of standards development by IEC is similar to the methods employed by ISO. The recognized national standards institutes with responsibility for development of standards for electrical products are IEC members. ANSI's U.S. National Committee is the U.S. member of IEC, and other U.S. voluntary consensus organizations may participate in IEC's standards development process through its technical committees (169).

Other International Standards-Setting Organizations.—The organizations with specific areas of interest contribute their expertise to the development of those standards. Many of these international voluntary organizations maintain close liaison with their national counterparts in the United States. The governmental role in these associations is limited to the extent that an individual member of a national professional society may also be a government employee and as such have contact with her or his international counterparts in the exchange of information.

The International Committee for Standardization in Hematology develops reference materials and recommends standardized techniques in diagnostic hematology, blood transfusion practices, and related activities.

The International Union of Immunological Societies and the International Federation of Clinical Chemists develop specifications for methods of testing and materials and also receive and organize international tests to submit to the World Health Organization (WHO) for acceptance as recommended procedures. WHO also develops and promotes standards in medical devices. Expert panels and committees of WHO have worked on such topics as standardization of diagnostic equipment and quality control in health laboratories.

The International Organization for Legal Metrology (OIML) is a treaty body established in the early 1950s. It is comprised of 48 countries, including the United States, which joined in 1972. OIML works to harmonize international standards for legal measuring devices, such as gasoline pumps and weight scales, and, in the medical field, such devices as blood pressure gauges and electrocardiographs. The National Bureau of Standards represents the United States in OIML. A U.S. advisory committee for legal metrology—consisting of representatives of Government agencies concerned with legal measurements, manufacturers of measuring devices, and major standards organizations such as ASTM and ANSI—provides guidance to the National Bureau of Standards when it represents U.S. interests in OIML.

Many international and regional trade associations participate in developing their own standards, and contribute to organizations such as ISO and IEC. Some of these associations represent manufacturers of radiation equipment, surgical instruments, and clinical laboratory materials.

European Standards-Setting Organizations

Because of the large number of countries in Europe, with their varied political, social, and economic systems, the environment is a "complex scenario against which to review standards and regulations applying to health care" (73). In addition to the government-affiliated and independent standards institutes within the various countries, there are also regional standards-related organizations.

The membership of the European Committee for Clinical Laboratory Standards represents health agencies, professional societies, and industry. Its objective is to improve clinical laboratory practices through a voluntary consensus mechanism (386).

The European Committee for Standardization (CEN) is composed of the national standards organizations of countries in the European Common Market, plus Austria, Finland, Norway, Portugal, Spain, Sweden, and Switzerland. Its major objective is to harmonize Western European implementation of ISO and IEC standards. In addition, it has developed approximately 60 "European Standards" in nonelectrotechnical fields. CEN operates certification systems, usually with respect to European Standards, and systems for recognition for test results for national certification programs where no European Standards exist (9).

The European Committee for Electrotechnical Standardization (CENELEC) is comprised of the national electrotechnical committees of its member countries. CENELEC seeks to harmonize the national electrotechnical standards of its member countries and uses IEC publications as a basis for its activities. Its major objective is to eliminate, through mutual agreement, any technical differences between the national standards and certification programs of its members that would result in trade barriers. In addition to its harmonization activities, CENELEC also develops European Standards in the electrotechnical field (9).

In general, each country has a national standards institute that produces or sanctions standards, much as does ANSI. These institutes also have technical committees comprised of government officials, manufacturers, and end-product users. For the most part, standards established by these institutes are voluntary; however, since each country has its own method of administering and monitoring compliance with these standards, the line between voluntary standards and mandatory regulations is often blurred (73). Therefore, it is useful to describe briefly key aspects of the standards setting and administering processes for several major European nations, namely the Federal Republic of Germany, the United Kingdom, and France.

In 1981, a group of international medical device manufacturers[2] formed the European Regulatory-Technical Affairs Study Committee, and conducted a study in the major nations of Europe on the state of regulatory affairs in the field of medical devices, including the diagnostic field. The resulting six-volume report contains a listing of government regulatory agencies, as well as information on certifying and testing organizations and on national standards-setting. This report indicates that there is an increasing trend for development of standards in Europe (102).

Federal Republic of Germany.—Two national laws govern most of the Federal Republic of Germany's governmental involvement in standards-related activity: the Drug Law of August 24, 1976; and the Law on Technical Equipment and Devices of June 24, 1968, as amended August 13, 1979 (163). Although the Drug Law is directed primarily to the pharmaceutical industry, it defines "drugs" to include certain surgical dressings, surgical sutures, and diagnostic products within the term "fictitious drugs" (164,174). In addition, implantables are brought within the scope of the legislation once they are actually implanted (163).

The Drug Law is comprehensive and contains sections on manufacture, licensing and registration, clinical trials, recording of adverse effects, inspections, labeling, and advertising (174). The Ministry of Health has statutory responsibility when problems with regulated products are reported and corrective action is necessary (163).

The Technical Equipment and Devices Law, administered by the Ministry for Labor and Social Affairs, sets forth standards for equipment safety. Special provisions require that a manufacturer certify that technical medical equipment is in proper condition and that either the manufacturer or an officially designated expert has subjected the equipment to final inspection. Equipment controls and operating instructions must incorporate use of the German language or utilize standard symbols (164).

There are two principal standards-setting organizations in West Germany. The Verband Deutscher Elektrotechniker (VDE) develops standards and provides certification testing and listing services for electrical components and systems. The other, the Deutsches Institut für Normung (DIN), is a voluntary consensus standards organization that has developed standards in a number of areas. Standards involving electrical aspects are often published jointly by DIN and VDE. In addition, there is a major testing-certification organization called the Technischer Überwachungs Verein (TÜV) which deals primarily with complete products, rather than their component parts. TÜV issues a "GS" (Geprüfte Sicherheit) mark that, although not mandatory, carries with it the same sort of prestige as the UL mark in the United States (293, 135).

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[2] Becton-Dickinson-France, S. A.; Beiersdorf A. G.; Cordis Dow, B. V.; Johnson & Johnson, Ltd.; Medtronic France, S. A.; Miles Laboratories, Ltd.; 3M Europe, S. A.; Travenol International Services, Inc.; and Welcome Reagents, Ltd.

United Kingdom.—In the United Kingdom, with its national health system, the Government is the primary user of medical devices. The Medicines Act of 1968 requires full premarket evaluation for drugs and medicines and sets forth requirements for licensing, manufacturing, inspecting, testing, and labeling. Certain medical devices, such as surgical sutures, dental filling substances, contact lenses, intrauterine contraceptive devices, and certain radioactive medicinal products, have been brought within the regulatory framework of the Medicines Act (174).

The British Standards Institution (BSI) is a voluntary standards-setting organization that was formed in 1901. In addition to its standards-developing activities, BSI also provides testing and certification services. Although the standards developed by BSI are voluntary, the Department of Health and Social Security (DHSS) has issued a recommendation that governmental purchases of medical devices comply with existing BSI standards (149). Therefore, medical devices manufacturers regard BSI standards as mandatory in practice, as they must be met in order to market devices effectively in the United Kingdom.

As BSI standards cover only a relatively small number of medical devices, DHSS general specifications, technical requirements, and voluntary "good manufacturing practices" have been developed to fill this void. Through its Scientific and Technical Services Branch, DHSS has also established a registration scheme for manufacturers. The role of that branch is to develop, in conjunction with various trade associations, suitable standards for quality assurance or good manufacturing practices, to assess the manufacturers' compliance with those general standards, and to publish a register of manufacturers complying with the good manufacturing practices (149). In the event that this voluntary scheme proves ineffective, the Medicines Act provides for residual authority to extend its scope to cover all medical devices (163).

France.—In France, the authority to control medical devices is derived from the Ministry of Health and Family and the Ministry of Industry. The two major mechanisms for control are the French Pharmacopeia and a "homologation" system (a system of official approval) (174).

The Ministry of Health and Family publishes Pharmacopeia monographs that contain specifications and descriptions for many sterile products, a variety of plastic products, surgical dressings, sutures, various tubing, and absorbent cotton. Requirements dictated by the Pharmacopeia are technically applicable only to products sold to public institutions (which account for over 90 percent of all medical facilities in France) or to products that claim to conform to the Pharmacopeia (164,293).

The homologation system is a process of obtaining official government approval applicable to a listing of devices that is periodically reviewed and updated. Although approval is mandatory only for products purchased by public institutions, the homologation system is linked to reimbursement procedures under the French social security system. Therefore, approval is necessary whenever a purchaser wishes to apply for reimbursement (164). Until recently, approval had been granted by an interdepartmental commission, and product-specific requirements, specifications, and procedures for testing were stipulated by decree.

In January 1983, France introduced an entirely new scheme of approval. Although it is unclear how the new scheme will operate in practice, the interdepartmental commission has been abolished, and a National Committee of Homologation, which has full responsibility for the approval process, has been created within the Ministry of Health and Family. The National Committee has five subcommittees, composed of experts drawn from the ministries, hospitals, and universities, and charged with defining the homologation procedures. The subcommittees operate in the areas of: imaging, operating theaters, artificial organs and prostheses, anesthesia and reanimation, and diagnostic equipment and monitoring (163).

In general, approval requests must be presented to the Ministry of Health and Family by an authorized agent established in France, and a testing laboratory will then be assigned. In practice, only laboratories within the Groupment des Laboratoires des Materiels de Technique Medicale are adequately equipped and staffed to do the work. For an electrically powered product, the French Electrical Code is applied as the minimum standard. If a particular product standard exists, it is also applied. Clinical testing may be required by physicians assigned by the ministry (293).

The Association Francaise de Normalisation (AFNOR) is France's primary standards organization. AFNOR is a private, public service association that centralizes and coordinates all work and studies concerning standardization, much as does ANSI. Formed in 1926, AFNOR is a voluntary organization of manufacturers, consumers, professional associations, and government representatives. Standards developed by AFNOR are voluntary; however, they may become mandatory if adopted for use within the homologation system. In 1943, AFNOR was given governmental authority to develop public standards and to administer the mark "NF" as indicating conformity with a standard.

Other Foreign Organizations

Japan.—The Ministry of Health and Welfare regulates the importation and sale of medical devices pursuant to the Pharmaceutical Affairs Law. In July 1983, an omnibus bill was passed making extensive changes in Japan's standards and certification system. The omnibus bill is the culmination of over 4 years of bilateral discussions between the United States and Japan (121).

Standards in Japan are normally developed through advisory committees to Japanese Government ministries (359). The Japanese Industrial Standards Committee (JIS) within the Ministry of International Trade and Industry is of particular importance to the medical devices industry. Products conforming to JIS standards and testing requirements are entitled to bear the "JIS" mark, which is the most prominent and widely used certification mark in Japan.

Prior to passage of the recent amendments, only JIS standardized medical devices were exempt from the approval process. The new legislation permits certain non-JIS standardized devices to bypass the approval process. The devices exempted are those for which the utility, efficiency, and safety is generally acknowledged, including such items as surgical knives, tweezers, medical scissors, sterilizers, operating tables, and stethoscopes (121).

Canada.—In Canada, the Department of National Health and Welfare's Bureau of Medical Devices (BMD) is the central point for mandatory standards. Under the Food and Drug Act of 1953, the department was granted authority to adopt standards and create regulations for medical devices. To date, BMD, which was created in 1975, has developed seven medical device regulations: 1) contraceptives, 2) cardiovascular pacemakers, 3) hearing aids (revoked in 1979, but the bureau is working to have them reestablished), 4) mobile oxygen inhalators, 5) blood collection tubes, 6) disposable insulin syringes, and 7) electromedical devices. In developing these standards, BMD examined existing national voluntary standards and other international and foreign standards which could be adopted or modified, and then based its standards upon a synthesis of them.

The Canadian Standards Association (CSA) is a voluntary, nonprofit, autonomous organization that provides standards-writing and certification services. Its members are drawn from the industrial, governmental, private, and educational sectors. In the mid-1970s, CSA initiated a Health Care Technology Program, whose goal is to develop consensus standards in the medical engineering field and to implement those standards throughout Canada through education, professional societies, and provincial or federal legislation (90). CSA is also a testing house for certification of medical devices. Manufacturers can pay to have their products certified as complying with CSA standards and certain other relevant standards.

The majority of Canadian medical device standards are not mandatory. However, since almost all of Canada's hospitals are public, various provincial governments require that certain medical devices meet CSA's standards or some other national, international, or foreign standard, such as those of AAMI or ISO.

This requirement has the effect of making many voluntary standards mandatory in operation. For example, all electromedical equipment sold or used in any Canadian province must be "approved," which in effect means that the product must be shown to conform to CSA standard C.22.2 No. 125 (90). Although certain CSA standards are substantially similar to UL standards in the United States, CSA does not automatically certify products certified by UL, but conducts its own testing (463).

Like ANSI (the American National Standards Institute), the Standards Council of Canada, a nonprofit organization, coordinates other standards-setting organizations and sanctions the standards developed by these bodies.

Mexico.—The Mexican Government has no uniform system of standards development that affects medical devices (301). The importation of medical products is governed only by the customs law and not by medical device or pharmaceutical legislation as in other developed countries. Entry requires a certificate of origin and description of the product. If a product bears a certification of compliance with the standards of the producing country, such as a UL mark, this certification is generally accepted by customs officials.

Change in the enforcement of customs laws in Mexico can generally be traced to national and international economic policy issues, such as the effect of imports on Mexican employment and other such economic concerns. These reasons usually are not directed at control of the quality, safety, or effectiveness of the products (301).

U.S. Government Agencies Involved in Standards-Setting Related to International Trade

The GATT Standards Code establishes new international ground rules in the area of technical (nontariff) barriers to trade. It sets forth international rules among governments for regulating the procedures by which standards and certification systems are prepared, adopted, and applied and by which products are tested for conformity with standards (359,380). The basic premise of the code is that standards-related activities should not be used as mechanisms to restrict unnecessarily international trade (46).

Although the code is directly binding only on the central governments of its signatories, these governments are obliged to take reasonable measures to ensure that regional, State, local, and private organizations also comply with the code's provisions (359). Therefore, the code provisions affect governmental and nongovernmental standards, whether voluntary or mandatory, and whether developed by central, regional, State, or local governments or private sector standards organizations.

Three U.S. Government agencies play a significant role in the implementation of the Standards Code in the United States: the Office of the U.S. Trade Representative, the Department of Commerce, and the Department of Agriculture (380). The Department of Agriculture's role, while important with respect to overall implementation of the code, is beyond the scope of this paper. Activities within the Department of Health and Human Services are outlined below.

U.S. Department of Health and Human Services

The National Center for Devices and Radiological Health in the Food and Drug Administration (FDA) frequently interacts with domestic and international voluntary standards-setting organizations. Domestically, the national center contributes to the review and development of standards by organizations such as ANSI, AAMI and ASTM.[3] FDA also participates in development of international standards through its work on the technical committees of both ISO and IEC. However, U.S. Government agencies have neither control over nor any official leadership role in the domestic or international private voluntary standards-setting process.

Recently, U.S. Government agencies—specifically FDA—have increased their participation in voluntary standards-setting activities because of two Federal policy initiatives: the GATT Standards Code, as implemented in the Trade Agreements Act of 1979 (19 U.S.C. §§ 2531-2573) and Office of Management and Budget (OMB) Circular A-119. Both of these policy initiatives establish guidelines for and encourage Federal Government agency participation in domestic and international voluntary standards-setting activities.

The Trade Agreements Act recommends the use, where appropriate, of international standards as the basis for developing domestic standards. FDA's work with voluntary organizations is important, therefore, to ensure that the U.S. view is expressed and that internationally developed standards are consistent with U.S. national standards in terms of product safety and effectiveness.

OMB Circular A-119 sets forth as Federal policy that the U.S. Government will rely on voluntary standards, both domestic and international, where appropriate, in lieu of governmentally developed standards. Circular A-119 also specifies that Federal employee participation should not in any way attempt to dominate the voluntary process (21).

The Centers for Disease Control (CDC) has also been active in voluntary standards-setting activities in the medical devices field. CDC provides technical assistance to organizations such as the National Committee on Clinical Laboratory Studies through CDC's work with various professional societies and through information received from State health departments and other public and private medical laboratories.

Office of the U.S. Trade Representative

In connection with its responsibility for setting and administering overall trade policy, the U.S. Trade Representative (USTR) coordinates the development and execution of the U.S. standards-related trade policy (419). USTR is responsible for resolving standards-related trade disputes between the U.S. and foreign governments, overseeing the general implementation of the Standards Code in the United States and coordinating the international trade activities of other U.S. Government agencies that engage in standards-related activities that may significantly affect trade, and negotiating bilateral standards arrangements (380).

Under the Standards Code, any signatory may question another signatory's compliance with code provisions. Bilateral or multilateral consultations are encouraged to resolve disputes. In the United States, a private party may informally raise with USTR a foreign practice that appears to be inconsistent with the code or otherwise denies benefits to the United States under the code (380). USTR will then pursue the resolution of problems, keeping the complaintant apprised of its activities. Problems arising under the code usually involve: failure by signatories to provide adequate information on their standards-setting activities, failure by importing governments to adopt standards set by international organizations, nonacceptance by importing countries of test data generated in the United States, and denial of access to certification systems (359).

U.S. Department of Commerce

National Bureau of Standards (NBS).—NBS has been delegated the responsibility for establishing and maintaining the U.S. inquiry point for Standards Code matters, the central repository for standards and certification information, and a technical office for nonagricultural products. The responsibilities delegated to NBS are carried out through the Office of Product Standards Policy's Standards Code and Information program.

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[3] FDA's activities regarding mandatory performance standards are discussed in ch. 5.

As the U.S. inquiry point mandated by the Standards Code, staff of the Standards Code and Information program notify the GATT Secretariat of proposed U.S. regulations potentially having an effect on trade. They receive notices and information on proposed foreign regulations and disseminate the information through several media and directly to interested U.S. parties. A primary objective of the notification program is to encourage review and comment on proposed foreign regulations. Foreign notifications are routed through various Government agencies, such as the Bureau of Industrial Economics in the Department of Commerce (DOC); agency members of the Interagency Committee on Standards Policy; private standards organizations; and industry groups.

This program also operates the National Center for Standards and Certification Information, which is the national repository for standards documents. The center responds to general inquiries about the existence of specific standards and regulations and maintains a reference collection of voluntary and mandatory U.S. standards, as well as major foreign and international ones. The technical office within the program provides assistance in the areas of exchange of information and dispute settlement.

To market products in foreign countries, U.S. exporters must be informed of the testing procedures, approval programs, and certification rules in effect in those countries. To date, there are no centralized or accessible reference collections that can provide exporters with this essential information (359). Current funding and staff resources within the Standards Code and Information program are insufficient to allow it to expand effectively into this area (1,91). However, the center has begun to collect certification information on an informal basis through its collection of materials on foreign and international standards activities and through information provided by U.S. trade and professional organizations.

International Trade Administration (ITA).—The Trade Agreements Act directs the USTR and the Secretaries of Commerce and Agriculture to consult with the private sector for technical and policy advice on the implementation of the Trade Agreements Act and the Standards Code (46,359). In order to meet its responsibilities, DOC has established an Industry Functional Advisory Committee (IFAC) on Standards for Trade and Policy Matters. IFAC, administered by ITA in DOC, is composed of approximately 20 members drawn from Industry Sector Advisory Committees within DOC and an approximately equal number drawn from private sector groups involved in standards-related activities (359).

IFAC is responsible for advising USTR on matters concerning trade, the operation of existing trade agreements, and other matters connected with U.S. trade policy. IFAC provides detailed policy and technical advice, information, and recommendations concerning standards and their effect on trade and the implementation of the Standards Code (359).

Although the mandates of the Standards Code are technically applicable only to the Federal Government, the Trade Agreements Act legislation calls on the President to promote adherence to the code principles by State and private sector bodies (19 U.S.C. § 2533). To this end, ITA has issued voluntary procedural guidelines for State and local governments and private sector organizations engaged in standards development, product testing, and certification systems (314).

Representation of U.S. Interests in International Standards Organizations.—The Trade Agreements Act directs the U.S. Secretaries of Commerce and Agriculture to keep adequately informed of international standards-related activities, to identify those activities that may have a substantial effect on U.S. commerce, and to coordinate those efforts with USTR. Although the act does not designate any specific private organization as the "official" representative of U.S. interests, it confirms the role of U.S. member bodies in private international standards organizations, such as the ANSI/ISO relationship.

The Secretary of Commerce has authority to determine that a member body is not adequately representing U.S. interests and to make arrangements for adequate representation (380). For any governmental international standards organizations in which U.S. interests are represented by one or more Federal agencies, the Secretary is directed to encourage cooperation among the agencies to seek a uniform position. In addition, the Secretary is directed to encourage such Federal agencies to seek information from and cooperate with any affected domestic industries (380).

The Standards Code and Information program fulfills DOC's obligations with respect to ensuring adequate representation of U.S. interests in international standards-setting through two major activities. First, the program's technical office responds to any information, complaints, or criticisms concerning participation in international standardization activities. Second, the program maintains statistics and information on U.S. participants in international standards-related activities (359).

Problem Areas for Medical Devices Standards in International Trade

At an OTA workshop in August 1983, representatives of selected members of the Health Industry Manufacturers' Association (HIMA) identified certain problems related to standards and international trade. All the participants came from large companies that engage in foreign trade. Although their views may not be generalizable to the medical devices industry as a whole, they do indicate the experiences and perspectives of companies from several areas of medical devices (see app. B for a list of workshop participants). It should also be borne in mind that a complete examination of standards-setting would require consideration of the benefits to purchasers and users of devices. This section discusses issues raised at the workshop as well as information from Government agencies and other industry representatives.

Development of Standards

Rationale or Need for Standards.—Workshop participants commented that insufficient attention is given to the rationale for developing standards. Developing medical device standards may proceed with little or no demonstration of concerns related to clinical safety and effectiveness (118). For safety standards that are engineering- or technology-based, much time and effort may go into creating standards important from an engineering point of view but of limited concern from a medical point of view. One way to demonstrate that a standard is reasonable is to include a rationale that defines the standard's purpose and limitations (118).

A related comment was that many standards are developed without any attempt to examine costs and benefits. Highly restrictive, costly, hardware-oriented standards are produced where adequate nonhardware alternatives (such as education, training, and preventive maintenance) for resolving the problem may exist. Publication of a rationale would facilitate public review and comment and would permit more appropriate application of standards (89).

The workshop participants advocated greater clinical input into standards development. Recently, a trend to involve medical professionals has been developing, particularly in the United States and in Canada, but many medical professionals appear reluctant to take the time away from their practices (or other responsibilities) or incur the expenses connected with participation. Consequently, standards may contain requirements that differ from those necessary to assure the safety and effectiveness of medical devices (145).

There was speculation that some foreign countries have reacted to the 1976 Medical Device Amendments by promulgating their own standards, both voluntary and mandatory. The question was raised of whether or not standards are needed, considering that many manufacturers produce devices to specific internal corporate standards based on current scientific and technical information, the marketability of the devices, and protection of the company from personal injury liability.

Access to Information.—When standards—domestic, foreign, and international—are being developed, it is often difficult for an individual or company to gain timely access to information so that comments can be submitted. A major objective of the Standards Code is to make standards-setting and certification activities open to all interested parties, and code signatories must follow certain procedures for new or amended mandatory standards and certification system rules (380). However, few foreign countries have detailed specific requirements regarding public notice, and the Standards Code requirements speak only in terms of reasonableness. Although none of the code signatories maintain notice procedures that actually violate the code, U.S. manufacturers have encountered difficulties in obtaining the timely, adequate information necessary for making meaningful comments (359).

FDA's notices of proposed standards development may not give enough information about the purpose or rationale to determine the scope or need for comments (21 CFR pt. 866). At the local level, users of standards, manufacturers, or consumers are not all members of national organizations and do not all subscribe to the publications (such as the *Federal Register* for domestic notices and the *Commerce Business Daily* for foreign notices) in which notices are published. Consequently, they may not take part in the comment process.

In January 1980, HIMA surveyed its membership to obtain information regarding members' international marketing activities, monitoring of regulations and product standards, and participation in foreign industry organizations. According to the survey results, manufacturers typically rely on foreign agents and distributors for information on changes in foreign regulations and product standards, and many have designated a specific employee, stationed either in the United States or abroad, to monitor standards-related developments.

Whereas over 70 percent of the manufacturers responding to the survey relied on distributors, agents, and employees as information sources, 35 percent of the respondents obtained information directly from U.S. Government sources and 21 percent obtained the information directly from foreign governments or foreign industry organizations (146).

Some European countries with only a few manufacturers in specialized fields such as medical devices have developed standards swiftly. These standards are often based on locally manufactured products and may, in fact, serve to restrain import trade. The standards-setting government may justify its standards by asserting that they are based on international standards "with qualifications," but the qualifications may be substantial and belie the original standard. Because these standards are often quickly enacted, U.S. standards organizations and interested manufacturers often have difficulty submitting comments in a timely manner. Once these standards are finalized, U.S. manufacturers may have difficulty in having their products conform to the foreign standards.

Suitable Representation.—The expense of analyzing drafts, preparing comments, and attending international meetings often makes it particularly difficult for small companies to participate, since the cost of participation is the burden of the individual committee members. In the private sector, it is usually the manufacturer who pays the expenses of the employee representative. The review and comment work of committees usually takes place over a period of months, or years in some cases. As a result, the interests of small manufacturers (and others unable to attend international meetings) in international standards-setting are often not taken into account.

Although 98 percent of the manufacturers responding to the HIMA survey were involved in the export or foreign manufacture of medical products, only 27 percent indicated membership in foreign industry organizations and only 25 percent reported active direct involvement in international standards organizations. The manufacturers that did participate in international standards development reported employee participation in various technical committees of organizations such as IEC, ISO, NCCLS, and OIML—as well as the national standards organizations of Australia, France, West Germany, and the United Kingdom (146).

Even with improved representation in international standards setting, U.S. interests may be unable to influence decisionmaking at the international level. European countries involved in the regional standards setting activities of organizations such as CEN and CENELEC often vote as a bloc in ISO or IEC to establish European technology as the basis for international standards (249).

Application of Standards

Cost of Conforming to Standards.—In the United States, UL or NFPA standards are often specified in public municipal codes, such as building and safety codes, or in purchasing specifications. Products must then bear a UL mark or other form of approval to be used within those jurisdictions. A device may be subject to design and performance standards as well as installation and use standards. Each time a test is conducted, additional costs are incurred. For example, some electrical devices require a UL mark as well as conformity to NFPA fire and safety codes. In addition, a foreign government might require different or additional tests and markings for the same product.

Although manufacturers consider some medical devices standards, such as those developed under the 1968 Radiation Control for Health and Safety Act, to have significantly improved the safety and quality of the products, they also maintain that the improvements have raised the cost of research, development, and final products.

In foreign countries, the cost to a U.S. manufacturer of complying with foreign standards that differ from domestic standards must be built into the price of its products. This can make U.S. products more expensive than local foreign ones, and thus less cost competitive. To minimize the costs of additional testing or procedures related to meeting foreign and domestic standards, as well as for other reasons, U.S. manufacturers have set up overseas operations. Establishment of foreign manufacturing subsidiaries by U.S. companies diminishes the balance-of-trade advantage for the United States.

Interpretation and Reliability of Information.—The existence of an international or foreign standard, and knowledge of its existence by a U.S. manufacturer, has only limited value. It is more important to the manufacturer to know how that standard will be interpreted by local or national officials, or other certifying bodies such as testing laboratories, government reimbursement agencies, or insurance providers.

In the Federal Republic of Germany, for example, there are DIN standards for medical device components, but within the country the officials of the various states interpret these standards differently. Differing interpretations can result in costly delays in supplying products or in cancellations of orders and contracts. In Germany, U.S. importers also face problems relating to insurance coverage. For example, although not legally required, a customer's insurance carrier asked the importer of an ultrasound imaging device to certify that the product met radiofrequency interference standards (235). This action caused considerable expense to the manufacturer in legal fees and delayed introduction of the product.

This situation occurs in other countries as well where the ultimate legal responsibility for radiofrequency interference (or any other responsibility for equipment safety or performance) rests with the user as opposed to the manufacturer. In order to obtain insurance coverage in these situations, the user's case is much stronger if it can be shown that the product meets, or has been certified to, the requirements of an applicable standard (293).

Most companies doing business internationally must rely on their market researchers to identify standards or other requirements that they must meet or on local distribution agents for their knowledge of local administrative procedures. Obtaining information through these sources is costly and time-consuming. It is all the more difficult for those companies that cannot afford researchers or local agents.

Once manufacturers have obtained information regarding foreign standards-related practices, they often encounter difficulties in confirming the accuracy of that information and determining its practical implications. A major difficulty in foreign standardization activities is determining what is required versus what is customary or desirable in certain markets. Manufacturers report that certain foreign standards requirements that appear to be mandatory may in practice be negotiable with the inspector.

For example, in the United Kingdom, one manufacturer succeeded in overcoming a seemingly mandatory DHSS radiation protection standard for X-ray equipment that contained an unworkable limit on fluoroscopic exposure. Through negotiations with the inspector involved, the manufacturer was able to obtain approval of its product (235).

Effect of Standards on Innovation.—The interpretation of standards by foreign governments and the reliability of information can be linked to the issue of how standards keep pace with new technologies. Some countries, such as Mexico, reportedly use out-of-date standards and have rejected products not meeting these standards. A recent example involved implantable pacemakers (301).

Although some standards have provisions for assessing new or improved products, others are written to preclude newly developed or improved products, such as the replacement of digital monitors for analog equipment. If standards are not written to accommodate product changes, introduction of new technologies will be restricted by existing standards and will serve as a barrier to trade.

The process of changing standards, especially international standards, is often as long and cumbersome as the initial development process. New technological innovations in medical devices may thus be barred from certain countries, either voluntarily or involuntarily, because the standards for the devices have not evolved so quickly as the products themselves.

Appendix I.—Governmental Regulation of International Trade in Medical Devices: United States, Canada, Japan, United Kingdom, France, Federal Republic of Germany, and Mexico[1]

United States

Regulation of Imports

Two types of government regulations affect the ability of foreign medical devices to compete in the U.S. market. The principal focus of this appendix is the first type—those regulations that directly impose requirements on foreign manufacturers and importers, or on the imported device itself. The second type of regulation indirectly influences the actual sales of imported medical devices by affecting their competitiveness with devices manufactured in the United States.

The regulations of the Food and Drug Administration (FDA) are designed to ensure that only safe, effective, and truthfully labeled medical devices are sold in the United States. In theory, this means that foreign manufacturers and imported devices must meet the same criteria as U.S. firms and domestically manufactured devices. In practice, however, because of budgetary constraints, foreign manufacturers of medical devices are treated somewhat differently, since they are not inspected so regularly as domestic manufacturers, and, unlike their domestic counterparts, they receive advance notice of an upcoming inspection.

The Customs Service, which is supposed to ensure that medical device importers comply with the general rules applicable to all imported products, in 1979 delegated certain of its general responsibilities to FDA (304).

Requirements of the Food and Drug Administration.—FDA regulations impose a number of requirements that must be fulfilled before a device can even be considered for import approval, and these requirements are the same as those imposed on domestic manufacturers (see ch. 5). Registration of a foreign manufacturer of medical devices is voluntary, but FDA tries to encourage such establishments to register. Registration is mandatory for the importer (initial distributor) of a foreign medical device (21 CFR 807.20, 1982). Unless the importer is registered, FDA will not allow the import to be released for sale in the United States.

A foreign manufacturer or distributor must also supply FDA with a list of every device that it exports to the United States (21 CFR 807.40, 1982) or authorize an exclusive distributor to file the medical device listing on its behalf. Failure to list a device will result in its exclusion from the United States.

Foreign manufacturers, unlike domestic producers, usually have at least 30 days notice prior to an FDA inspection. Because of the expense and logistics involved, foreign inspections by FDA are infrequent. Furthermore, it is likely that they will become even more infrequent in the future because of recent reductions in FDA travel funds.

The third set of FDA preimportation requirements involves premarket notification and approval. The scope of these requirements varies based on the nature and history of the product. If a product was being imported into the United States prior to the Medical Device Amendments of 1976, it may continue to be imported without notification. But if a device was not being imported prior to 1976, the manufacturer or importer is required to submit a premarket notification to FDA. If FDA finds that a product is substantially equivalent to a preamendments device, importation and marketing will be permitted. If a device is not substantially equivalent to a preamendments device, it may be subject to the further requirement of premarket approval (see ch. 5). In that case, neither importation nor marketing of the device is permitted until approval is received from FDA.

The fourth form of preimportation requirement relates to manufacturing. Both foreign and domestic manufacturing establishments are subject to inspections to ensure compliance with good manufacturing practices, although the right of such inspection may be limited by foreign governments or the foreign firm involved. If a satisfactory arrangement for an inspection cannot be made, FDA has the authority to exclude the product since it would be unable to determine whether the device met the good manufacturing practices requirements of the Federal Food, Drug, and Cosmetic Act. (FDA has encountered few, if any, problems in inspected medical devices firms in the countries included in this appendix (204).)

Pursuant to a 1979 delegation of some of the Customs Service's authority, FDA monitors compliance with customs regulations, collects samples, issues notices of sampling, and issues notices of refusal of admission at certain ports (384). Figure I-1 outlines the steps involved in clearing customs.

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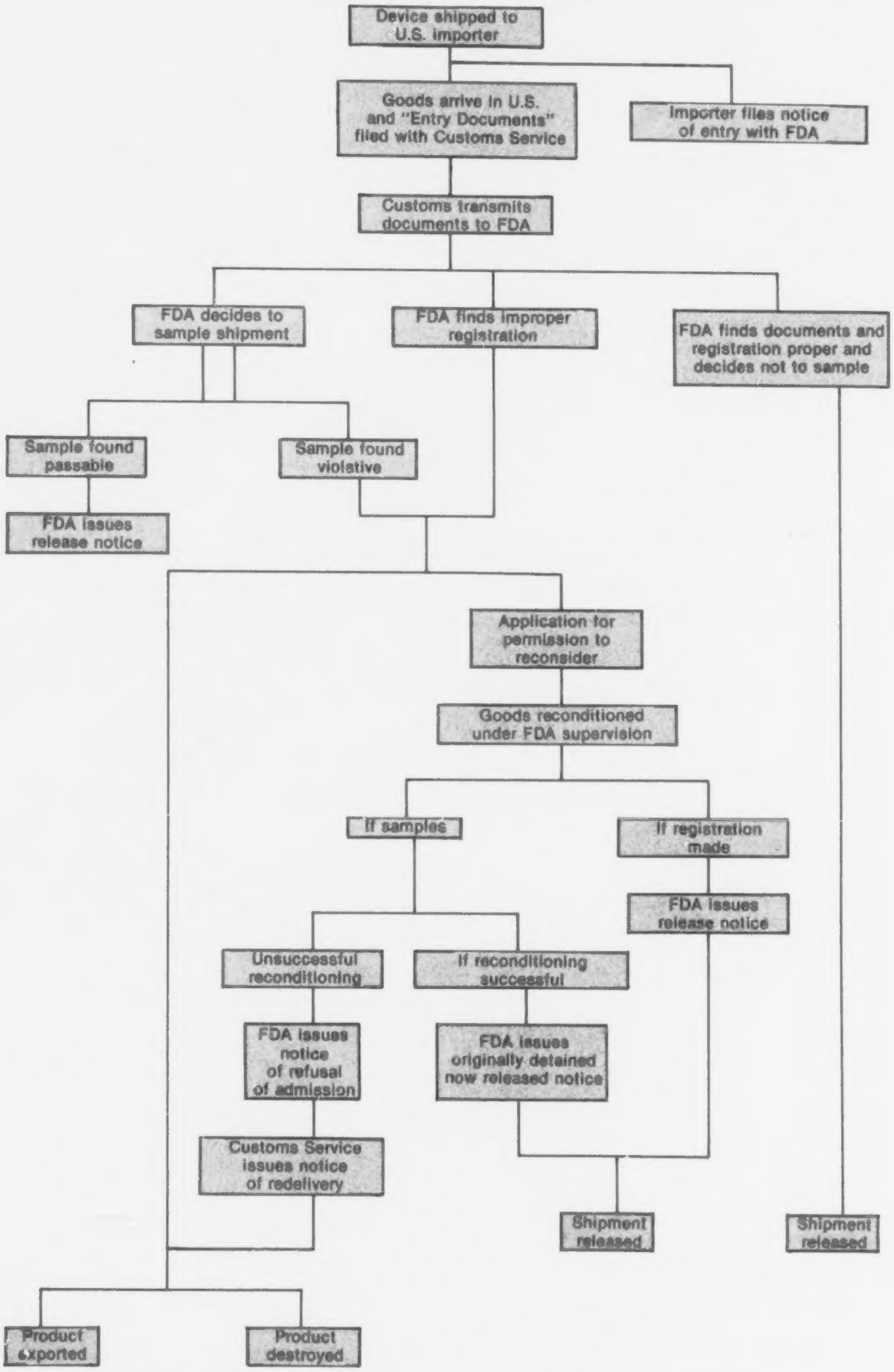
[1] Excerpted from a paper prepared for OTA by Kaye, Scholer, Fierman, Hays & Handler (181).

Figure I-1.—FDA Import Procedures for Foreign Medical Devices


Device shipped to U.S. importer
Goods arrive in U.S. and "Entry Documents" filed with Customs Service
Importer files notice of entry with FDA
Customs transmits documents to FDA
FDA decides to sample shipment
FDA finds improper registration
FDA finds documents and registration proper and decides not to sample
Sample found passable
Sample found violative
FDA issues release notice
Application for permission to reconsider
Goods reconditioned under FDA supervision
If samples
If registration made
FDA issues release notice
Unsuccessful reconditioning
If reconditioning successful
FDA issues notice of refusal of admission
FDA issues originally detained now released notice
Customs Service issues notice of redelivery
Shipment released
Shipment released
Product exported
Product destroyed

SOURCE: Office of Technology Assessment.

There is no evidence to suggest that FDA regulations were adopted for the purpose of erecting barriers to international trade in medical devices, or that they are administered with such an intent. As a practical matter, however, certain regulations do have a different impact on importers than on domestic manufacturers. For example, domestic producers may have an advantage with respect to participation in the notice and comment process and informal negotiations leading to the development of regulations. Not all regulations, however, operate to the advantage of domestic producers. For instance, due to logistical concerns, inspections under the good manufacturing practices regulations are more frequent, and undoubtedly more burdensome, for domestic producers than for foreign manufacturers.

FDA has a variety of administrative sanctions equally applicable to domestic and foreign manufacturers that can be used to prevent the marketing of adulterated or misbranded medical devices. There are, however, important practical distinctions between FDA's authority over domestic medical devices and imported devices. In domestic commerce, FDA has only formal statutory authority to bring enforcement actions such as seizures with respect to devices when those devices are actually misbranded or adulterated. FDA's discretion is therefore limited by the requirement that it be able to prove that a device is in fact adulterated or misbranded. FDA's enforcement authority over imported devices is broader; it has the authority to act when an imported device *appears* to be misbranded or adulterated (21 U.S.C. 381(a), 1976; (294)). The "appears" standard significantly modifies the usual burden of proof and offers more discretion to FDA to detain or otherwise halt potentially defective or hazardous medical devices before they are distributed to consumers in the United States. On the basis of this authority, FDA actively monitors imports to prevent the introduction of offending devices

On the other hand, it must be noted that FDA has a variety of informal administrative remedies, such as regulatory letters or recalls, which it employs where it does not wish to institute a formal enforcement action. Some of these actions may be more difficult to apply to foreign manufacturers than to domestic manufacturers.

Customs Service Regulations.—The result of the delegation of customs' authority to FDA is that the only customs Service regulations applicable to medical devices are those generally applicable to all imported products. These regulations fall into three categories: those pertaining to "entry" of goods into the United States, those pertaining to the assessment of duties on imported products, and those which pertain to the physical appearance of imported goods.

This classification system may change in the near future. The U.S. International Trade Commission recently prepared a study in anticipation of the conversion of the U.S. tariff classification into an internationally agreed-upon, harmonized system of tariff classification. If adopted, the system will result in a more uniform classification of medical devices between different countries, and thus make the gathering of statistical data easier, but it will have little economic effect on imports into the United States.

Tariffs applicable to medical devices are now generally in the range of 5 to 10 percent, which is comparable to the rates applied by other countries to the imports manufactured in the United States.

The third set of regulations administered by the Customs Service relate to the physical appearance of, and markings on, devices. Although these requirements must be met by importers, they have no significant impact on the pattern of trade in medical devices.

U.S. Trade Laws.—In addition to being subject to FDA and Customs Service regulations, imports of medical devices are subject to regulation under the general U.S. trade laws. These laws, which are briefly described below, can be used to impose additional duties, quotas, or other restrictions on the importation of medical devices that might cause injury to the domestic medical devices industry. There are two basic categories of such trade laws: those that impose restrictions when imports that are traded "unfairly" injure the domestic industry, and those that permit restrictions on imports where there is injury to the domestic industry, without regard to "unfairness."

The unfair trade laws have not often been invoked in the medical device area. Nor has any part of the medical device industry yet attempted to bring a countervailing duty or antidumping case against imported medical devices.

Two actions have been brought against importers of medical devices on the grounds of unfair trade practices. In June 1982, the U.S. International Trade Commission instituted an investigation involving certain computed tomography (CT) scanner and gamma camera medical diagnostic imaging apparatus. The investigation involved allegations that equipment imported from Israel violated a patent granted to a U.S. company (312). In March 1983, the commission made a preliminary determination that there was no violation and the case was terminated. In September 1983, the commission initiated a second investigation involving cardiac pacemakers and components (322). This complaint was also based on alleged patent infringement and is currently pending before the commission.

Regulation of Exports

In the United States, the export of medical devices is not regulated to anywhere near the same degree as imports. To the extent that export regulations do exist, they are administered principally by two agencies, FDA and the Office of Export Administration (OEA) in the U.S. Department of Commerce.

FDA Export Regulations.—For export purposes, medical devices can be divided into three categories. The first category of devices is by far the largest; any medical device that can be marketed legally in the United States can be exported legally from the United States without prior approval by FDA.

The second category of devices are those that cannot be marketed in the United States, but that can be exported without FDA approval if the product (sec. 801 (d)(1) of the Federal Food, Drug, and Cosmetic Act):

- meets the specifications of a foreign purchaser,
- does not conflict with the laws of the country of the foreign purchaser,
- is labeled for export, and
- is not sold or offered for sale in domestic commerce.

Prior FDA approval is not required for exports under section 801(d)(1), but FDA may at any time require an exporter to show that the exports that it is making under this section comply with the section's four requirements.

The third category of medical devices, those exported under section 801(d)(2) of the act, includes certain types of adulterated or misbranded devices that may be exported only with specific FDA approval and not under the less strict standards of section 801(d)(1). The third category specifically includes products that violate performance standards; that are subject to but have not received premarket approval; that are subject to limited investigational use, or that are banned in the United States. As a practical matter, most devices requiring FDA approval for export are those that require but have not yet received premarket approval or that are subject to limitations as investigational devices.

To obtain FDA approval for export of a medical device in the third category, an exporter must submit to FDA an "Export Request." This request must contain a description of the device and its status under U.S. law, and a letter of acceptance from the government of the importing state. This letter of acceptance must state:

- that the device is not in conflict with the laws of the importing state,
- that the foreign government has full knowledge of the status of the device in the United States, and
- that the import is permitted (along with any restrictions that might be imposed).

On the basis of this information, FDA will approve the exportation of the device if it would not be contrary to public health and welfare.

The FDA approval process for exports under section 801(d)(2) raises two problems for U.S. exporters. The first arises from the need to obtain explicit authorization from the foreign government for the importation of a device and is also faced by exporters under section 801(d)(1). Since many countries have no laws governing the approval of medical devices, it is difficult for these countries to inform FDA that a device is approved for import. In such cases, FDA will accept a statement from a foreign government that it has no laws prohibiting the importation of a particular medical device. This procedure may only partially alleviate the difficulty because in many of these countries no one is authorized by law to make even such a limited statement to FDA. The second problem is the vagueness of the "public health and welfare" standard used in section 801(d). Neither the Medical Device Amendments of 1976 nor the legislative history indicate whose health and safety is to be protected by FDA.

In practice, FDA's reliance on the standard is minimal; the decision to allow an export is usually made simply on the basis of whether the foreign government approves the importation of the device. From October 1, 1981 through September 30, 1982, FDA issued 260 letters approving export of medical devices under section 801(d). In the same period, eight requests were not approved. From October 1, 1982 through March 31, 1983, 116 approvals for export were given, five devices were not approved, and one previous approval was rescinded.

Department of Commerce Export Controls.—Medical devices, along with all other U.S. exports, are subject to the export controls in the Export Administration Act of 1979. That act authorizes the President to impose controls on exports for reasons of national security, foreign policy, and short supply.[2] The principal authority to administer these controls has been given to the Commerce Department's OEA; other agencies including the Departments of State, Defense, Energy, and Treasury have an advisory role in OEA licensing decisions.

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[2] The Export Administration Act originally expired on Sept. 30, 1983. The controls under the act were at first extended on a temporary basis by the President pursuant to the authority of the International Economic Emergency Powers Act. Congress later passed a bill extending the act until the end of February 1984. Congress is considering reauthorization with a variety of amendments, but it is not possible to predict what new provisions will be included.

All exports from the United States must be authorized by either a general or a validated export license. A general license is an authorization to export granted by regulation rather than by specific application. General licenses can be used to export any good to any destination, as long as neither the good nor the destination is controlled. Validated licenses are required whenever the export of a specific commodity is controlled to a specific destination.

Determination of whether a particular commodity requires a general or validated export license is made with reference to the Export Administration Regulations and the Commodity Control List.

Medical devices fall into several product classifications of the Commodity Control List, depending on the nature of the product and its technological sophistication. For example, most medical, surgical, and dental supplies are classifiable within the miscellaneous product group item 6999 G, "other commodities not elsewhere specified," which can be exported under general license except to Cuba, Kampuchea, North Korea, and Vietnam. Most X-ray equipment is classified in the Electronic and Precision Instruments Product Group in item 1533A, which requires a validated license to any destination other than Canada.

In most cases, the requirements applicable to medical devices are less than clear because the Government's interests in restricting exports are based not on their status as medical devices but on the fact that they include some form of technology that the United States wishes to control, such as computer or laser technology. An example can be seen in item 1522A, "lasers and laser systems including equipment containing them," for which a validated license is required for all destinations except Canada. Although most medical laser systems would appear to be covered by this classification, the explanation of this item in the Commodity Control List provides no further specific guidance. Treatment of medical equipment incorporating semiconductor or computer technology can be even more complicated and can depend on the speed of the computer, its capacity, the capability of the computer, and the materials from which the semiconductor is made. Thus, similar medical devices could be classified as different items, with one requiring only a general license and the other a validated license because the latter has a computer that operates at a slightly higher rate of speed or because its semiconductors are made of a different material.

This export control process and the intricate classification system raise the level of uncertainty for medical device exporters. Whenever a validated license for a transaction is required, an exporter cannot be sure whether the export will be approved, in what form it will be approved, or how long approval will take.

The eventual destination of the device raises additional questions. It is probable that export licenses will be granted for the export to Western Europe or Japan of a medical device incorporating controlled technology. Export of the same device to a country in Eastern Europe or to the Soviet Union may or may not be allowed, depending on the discretionary decision of the Commerce Department as to whether the release of the technology may hurt U.S. national security. Even if export approval is granted, conditions may be imposed, including substantial modification of a device in order to prevent the release of sensitive technology. The question for the exporter is whether a prospective buyer would be willing to accept a device that is significantly different from that which the buyer originally intended to purchase.

Regardless of whether the export of a medical device is eventually approved, the length of time involved in the licensing process is a disincentive to export. In most cases, the Commerce Department issues an export license in 4 to 6 weeks. This time frame, however, rests on the assumption that the export does not involve highly sensitive technology and is not destined for a sensitive country such as the Soviet Union, and that the exporter has supplied all the correct documentation to the Commerce Department. Delays occur when the exporter submits insufficient or incomplete information or when other agencies, usually the Departments of State and Defense, exercise their right to review an application. In such cases, delays of months and, in extreme cases, years may result.

A number of proposals currently being considered to facilitate export while protecting national security, such as elimination of export licenses to most Western European countries, reduction of controls in situations where identical technology is available from other foreign sources, and reconsideration of which technology is deemed to be militarily sensitive, may remove many medical devices from controls. Similarly, Administration moves to ease restrictions on exports to China will open up that market to increasing numbers of U.S. medical devices.

U.S. Government Export Promotion Activities

Department of Commerce.—Most Government export promotion activities are centered in the Department of Commerce. Among the department's export promotion activities are the Export Trading Company program, the dissemination of information about standards, the development of market research data, and the activities of the Foreign Commercial Service.

Under the Export Trading Company Act (Public Law 97-290) groups of U.S. exporters are able to combine their resources to aggressively seek export markets. Groups of medical device exporters or even a single medical device manufacturer may obtain a certificate from the Department of Commerce enabling them to engage in certain activities that would otherwise be prohibited under antitrust laws. There has been little experience in the operation of export trading companies, and it will be some time before it can be determined whether the program will in fact significantly promote U.S. exports. At the present time, no medical device manufacturers appear to have attempted to establish export trading companies.

A second Commerce Department function of potential significance to the medical device industry is the compilation by the National Bureau of Standards of lists of applicable foreign standards. This project has not yet been completed, but when it is, the ready availability of applicable foreign standards will be of help to U.S. medical device exporters. There is currently no compilation of medical device standards. FDA's Bureau of Medical Devices publishes an annual survey of standards for medical devices, but it simply identifies relevant standards of most major U.S. trading partners and does not reproduce them. The actual standards are available only from sources in the foreign country, or, in some cases, from private organizations in the United States, such as the American National Standards Institute, Inc.

The Department of Commerce also provides a variety of resources for potential exporters, including market research and computerized lists of market opportunities. The department has, for example, commissioned detailed market surveys of the medical device markets in a variety of countries. These Country Market Surveys include information about market conditions, the status of foreign competitors, the major end-users, and forecasts of the markets for particular medical devices. Also included are brief reviews of foreign government regulations. The department also maintains lists of potential purchasers of U.S. goods.

Although the services provided in the Department of Commerce are not a substitute for individual market analyses by an exporter and do not eliminate the exporter's need for competent assistance in the foreign market, they do provide some help, particularly to first-time exporters to certain markets.

Department of the Treasury.—The most significant financial export incentive provided by the U.S. Government and available to exporters of medical devices is the "DISC" export tax system. Under the DISC provisions of the income tax code, a corporation engaged in export trade may set up a corporation called a Domestic International Sales Corp. (DISC), through which it channels its export sales. It is then permitted to defer tax on portions of the income of the DISC. Under the complicated accounting rules applicable to DISC taxation, the amount of income thus sheltered varies, depending on the level of export sales made by the DISC, but generally up to 20 percent of the income generated by export sales can be sheltered.

The DISC system is currently under congressional review. International criticism of the DISC system as an illegal export subsidy persuaded the United States to make a commitment to its foreign trading partners to eliminate it. There are several possible replacements for the DISC system pending before Congress.

U.S. Trade Representative.—The U.S. Trade Representative (USTR) is the principal U.S. negotiator for international trade agreements. USTR represented the United States at the Tokyo Round of the Multilateral Trade Negotiations, held under the auspices of the General Agreement on Tariffs and Trade (GATT), which led to the development of the Standards and Government Procurement Codes. The Standards Code is an agreement among the signatory countries, including most major export markets for U.S. medical devices, not to use standards as nontariff barriers (see app. H). The Government Procurement Code is an agreement to expand the opportunities of foreign sellers to compete for Government contracts. By seeking to enforce U.S. rights under these agreements, and by negotiating for an expansion of their scope, USTR can play a role in expanding foreign markets for U.S. medical devices.

USTR also conducts bilateral negotiations to remove specific trade barriers to U.S. goods. The issues are usually brought to the attention of the USTR by private industry. For instance, USTR has been negotiating a reduction in Japanese medical devices trade barriers for the last year. The U.S. medical device industry brought to the attention of USTR a number of Japanese import procedures that had the effect of significantly limiting the access of U.S. products to the Japanese market. Among these barriers were regulations requiring chemical testing for devices, restrictions on changes in import agents, complex procedures for approving minor device changes that do not affect health and safety, and the generally slow process leading to approval of medical devices. Negotiations between the Japanese and USTR have had limited positive results, with some restrictive procedures having been modified to accommodate U.S. concerns (see below).

Canada

The Canadian market for medical equipment, including medical devices, was approximately $440 million in 1981 (241). By 1980, imports of medical equipment had reached an estimated $391 million annually, constituting 88 percent of the total market. By far the largest share of the imports, 82 percent in 1980, came from the United States, and many of the domestic Canadian medical device manufacturers are owned by U.S. firms. Canada has had universal health insurance since the early 1970s.

Import Requirements

There is no import license required for medical devices. However, under regulations issued by the Ministry of National Health and Welfare, it is illegal for any person to import for sale any device which does not meet the specific requirements relating to safety, efficacy, and truthful labeling of the Canadian Food and Drug Act or the Medical Device Regulations (255). As in the United States, goods found to be nonconforming may be relabeled or modified by the importer to meet Canadian requirements.

In addition, within 10 days of the first sale of a device in Canada, importers are required to provide information to the Health Protection Branch of the Ministry of National Health and Welfare regarding the foreign manufacturer or importer, the Canadian distributor, the model number, any drugs present in the device, statements of the uses for which the device is being offered, and the method(s) of sterilization, if any, recommended by the manufacturer.

Extra-oral dental X-ray equipment is subject to special import restrictions (254). Imported radiation-emitting devices must comply with all applicable standards regarding design, construction, and function. Canada will accept X-ray devices certified under U.S. FDA performance standards.

Tariffs on medical devices now average approximately 15 percent and are expected to be reduced to 9.5 percent by 1985 under GATT commitments already made by Canada (241).

Product Approval Process

Both imported and domestically manufactured medical devices are regulated by the Health Protection Branch of the Ministry of National Health and Welfare, which carries out laws such as the Radiation Emitting Devices Act, the National Health and Welfare Act, the Food and Drugs Act, and the Hazardous Products Act, which concern the types of information required to be submitted and the timing of the submissions.

Under the Canadian product approval system, the manufacturer or importer of a medical device must conduct premarket tests and present the results to the Health Protection Branch. The data must indicate the benefits and performance results claimed for the device. In addition, at any time the manufacturer must be prepared, if requested, to provide to the Assistant Deputy Minister of the Health Protection Branch information on test methods and test results (255).

Only recently has the Canadian Government begun to develop regulatory standards for medical devices. The Bureau of Medical Devices in the Health and Protection Branch of the Ministry is concerned with the technical and scientific aspects of medical device regulation regarding the quality, safety, and efficacy of medical devices (241). The bureau conducts research to allow it to enact specific safety and performance standards for various types of medical devices and to develop test methods to evaluate conformity with these standards. It also tests devices for compliance with standards, to assess manufacturer's claims for safety and efficacy, and to evaluate newly suspected hazards in previously approved devices.

In addition to its scientific duties, the bureau accumulates information on sales of medical devices in Canada and monitors recall developments in foreign countries. When appropriate, it also initiates recalls of imported devices.

Only a few types of medical devices are presently subject to mandatory standards promulgated by the bureau (241). In addition to the standards for radiation-emitting devices, there are now national standards on leakage of current from electromedical devices and the design and operation of oxygen inhalators. These standards tend to be similar, though not identical, to U.S. standards.

The bureau has also enacted regulations requiring premarket review of all implantable medical devices and submission by the manufacturer of safety and effectiveness data. It is expected that the bureau will issue additional standards for a number of medical devices in 1984—including labeling and packaging standards for radioenzyme testing devices, infant incubators, medical gas cylinders, and ozone emissions from medical devices.

Medical devices that are "new" within the definition of the Canadian Food and Drugs Act are subject to additional regulatory requirements first imposed in 1975 (255). At the present time, the only products that fit this category of "new" devices are intrauterine devices, cardiac pacemakers, prolonged-wear contact lenses, and intraocular lenses. Even these devices are considered new only if they have not previously been sold by the same manufacturer in Canada, differ from a device previously sold by the same manufacturer in Canada, or are identical to a device previously sold in Canada by the same manufacturer but recalled or withdrawn from the Canadian market. To be sold in Canada, new devices must receive a Notice of Compliance from the Health Protection Branch.

In addition, it is usually necessary for manufacturers of certain medical devices to comply with standards set by the Canadian Standards Association, an independent, private body. The association has two general specifications that govern X-ray equipment and electromedical equipment. Provincial governments enforce compliance with these standards (241).

Other Market Factors

Other than tariffs, which are temporarily somewhat higher than in the other developed countries in this study, the Canadian market remains remarkably free of direct and indirect import barriers. The health care delivery system does not discriminate overtly against purchase or use of foreign medical devices. However, the Canadian Federal Government has had a practice of granting a preference to goods of Canadian origin when making purchasing decisions. This has taken the form of accepting bids by Canadian suppliers that are within a specified range (5 to 15 percent) of the lowest bid offered by a firm importing similar goods.

Some provinces, particularly Ontario and Quebec, have adopted similar preferences for products from within the province. Although the Federal and Provincial governments purchase most of the medical devices sold in Canada, the effect of their procurement policies on imports has not been as great as might have been expected, probably because except for disposables the Canadian medical devices industry is not well developed.

Japan

The Japanese market for all medical equipment, including medical devices, was estimated to be about $1.24 billion in 1982 (122). The share of the Japanese medical equipment market held by imports has in recent years been only about 23 percent, one of the lowest percentages for any industrialized country except the United States. The United States is the largest supplier of medical equipment in Japan, providing approximately 60 percent of all such imports in 1982.

Import Requirements

Special technical import requirements apply to many products, including medical devices. When a device is subject to one of these technical requirements, a firm must apply to the Ministry of International Trade and Industry (MITI) for an import quota certificate. In addition, U.S. products that require an export license under the U.S. Export Administration Act or are subject to other U.S. export controls must also have an import certificate. Most medical devices are also subject to technical inspection at the point of entry to Japan to assure that any applicable standards have been met.

Under the Pharmaceutical Affairs Law, importation of medical devices into Japan must be approved by the Ministry of Health and Welfare unless the devices bear the Japanese Industrial Standards Committee (JIS) mark of approval (243). The term medical device includes instruments for use in the diagnosis, cure, or prevention of disease in man or animals, or intended to affect the structure or function of the body and which are designated by Cabinet Order.

Two types of licenses are necessary to import a medical device. The first is a license for professional importation, a general license required of all importers, which signifies that a company or person is qualified to sell medical equipment in Japan. The purpose of this licensing procedure is to ensure that each company importing medical equipment to Japan has the capability and knowledge to service the equipment and instruct purchasers in its proper use. Each office of an importing firm must be separately licensed for professional importation. These licenses are valid for only 3 years.

Each type of medical device to be imported must also be granted a separate product license, which is to ensure the quality, safety, and efficacy of the device (243). To be granted a license, the device, if it has not already received the JIS mark, must go through a time-consuming and rigorous testing and approval process. Virtually any modification in the design or type of a device being imported, even if it does not change the product's performance, requires a repetition of the product approval process discussed below, as though an entirely new product was being licensed.

Until August 1983, only an importer could apply for a product license. The theory behind this requirement was that the importer, rather than the foreign manufacturer, actually stood behind the device in Japan for product liability and all other purposes. For this reason, transfer of a product license from one importer to another was forbidden. The effect of this requirement was to limit drastically the ability of overseas suppliers to change their Japanese distribution agents, since switching agents required submitting a new product license application, causing delays of 6 months to 2 years.

In response to growing pressure from European and U.S. Government agencies (3) and trade groups, the Japanese Ministry of Health and Welfare in April 1983 announced planned changes in the importer and product licensing process (173). The most significant modification was that, effective August 1, 1983, a foreign manufacturer could apply for a product import license. The foreign manufacturer must submit the same documents and data relating to a device's safety and efficacy that are required of an importer applicant and designate an "in-country caretaker," who handles the responsibilities ordinarily imposed on a domestic manufacturer.

Approval of a foreign manufacturer's product import application also depends on the payment of all costs for an onsite inspection of the foreign manufacturer's overseas facilities. Theoretically, all U.S. manufacturers importing new devices to Japan will be subject to inspection. A "grandfather clause" limits the applicability of this new system to medical devices not currently on the Japanese market. A recent change in the regulations issued under the medical device law allows product licenses to be transferred from one importer to another in certain cases.

Japan applies GATT tariffs to medical devices. The rates now average between 6 and 8 percent and are scheduled to decrease by 0.5 percent on average in 1984 (122). Japan has adopted the basic Customs Cooperation Council Nomenclature (CCCN) for purposes of classifying imports, including medical devices.

Product Approval Process

Applications for approval of the product license discussed above are made to the local prefectural government and must be accompanied by the results of clinical tests conducted in Japan (242). If the device is identical to an already approved item or has received the JIS mark, approval by the Pharmaceutical Affairs Bureau is automatic. Otherwise, a minimum of two clinical studies conducted in authoritative general or university hospitals is required. Because tests conducted only on Japanese nationals are acceptable, U.S. firms have to repeat clinical tests in Japan that have already been conducted elsewhere (3).

The time elapsed between submission of an application and the receipt of final approval is a minimum of 3 months and can be as much as a year or more (215). The Government official responsible for the review need not inform the manufacturer in advance of the data needed and may require additional studies and information. As a result, considerable time elapses if the Ministry of Health and Welfare returns applications for more data.

Another problem that has been raised during U.S.-Japan discussions of medical device regulation is the need to apply to local prefectural offices, which then forward data to the Ministry of Health and Welfare. The U.S. Government has urged Japan to allow local prefectures to approve routine applications, such as changes in the color and size of a product.

JIS, a part of MITI, has broad powers to establish standards for industrial products. JIS standards are not usually identical to the corresponding international or U.S. standards. Although devices are not required by law to conform to JIS standards, and some domestically manufactured items that do not conform are actually sold in Japan, it is very difficult to import and sell products that do not conform to JIS standards.

Foreign manufacturers can apply for permission to attach the JIS emblem to their products under the Industrial Standardization Law (Law No. 185, 1949, revised 1980). Permission to use the mark is given on a plant-by-plant basis after an onsite inspection by officials of the applicable Ministry. Depending on the nature of the medical device, permission to use the JIS mark must be approved by MITI. JIS has promulgated hundreds of standards relevant to medical devices (122). The general standards are usually similar to the standards promulgated by the International Electrotechnical Commission. Specific JIS standards have been established for some electromedical devices including cardiographic, electroencephalographic, and audiometric. A program is now under way to put into place specific standards for 38 additional electromedical devices.

Under the Pharmaceutical Affairs Law, the Ministry of Health and Welfare has developed its own standards for certain medical devices such as contact lenses and artificial heart valves for which sterilization is particularly important. Products for which Ministry standards have been developed require for importation certification that they conform with the standards. Obtaining this certification involves testing samples in Japan.

Other Market Factors

Both established business practices and Government regulation hinder the importation of medical devices into Japan.

The Japanese Government has set up the GOTODA Committee to study ways of bringing the Japanese certification process and standards more in line with international practice (195). The committee's recommendations have led to Government modification of some regulations, such as the product import license scheme above. However, a number of regulatory barriers have remained, such as the requirements that clinical testing be performed on Japanese people; that electromedical devices remain at the point of entry until they have been inspected and approved for release; and that the product approval process be repeated for very minor modifications not affecting a device's performance or safety.

Many U.S. firms operating in Japan also believe that the Japanese Government enforces its product licensing requirements unequally, to the disadvantage of importers. Because the Ministry of Health and Welfare lacks a domestic enforcement arm similar to the FDA's field force, violations of the product licensing requirement may go undetected.

The existing system of distribution is also a stumbling block to expansion of the import market in medical devices. U.S. firms and their subsidiaries have generally relied on domestic sales agents to sell their products. Direct sales by importers to end-users were unheard of until the recent changes in Japanese regulations effective August 1, 1983. Direct sales will probably remain rare for a while, given the importance of personal ties to the market and the requirement that foreign firms wishing to sell to an end-user must obtain a license for professional importation which involves inspection of each plant where the product is manufactured. Such licenses, however, are not required for import sales to distributors or other firms that resell the equipment to end-users.

Although most U.S. manufacturers of medical devices have not had Japanese subsidiaries, a growing number of U.S. firms, including Beckman Instruments, Inc., American Hospital Supply Corp., and Baxter Travenol Laboratories, Inc., have set up subsidiaries to promote Japanese sales. Using subsidiaries assures buyers that the seller has the knowledge and ability to give proper instruction in use of the device and to service it after sale, both important factors in selling very sophisticated electromedical devices.

Sales to an agent remain the most common form of product distribution, not only for medical devices but also for many other imported products. However, the system of selling through agents results in one or more markups of the device's price, which pushes the price of foreign products above those of comparable Japanese products.

United Kingdom

The United Kingdom has traditionally been a major market for medical devices because of its extensive and sophisticated health care system. In 1982, total sales of medical equipment in the United Kingdom were in excess of $600 million (52). The size of the U.K. medical device market is linked directly to expenditures for the nationalized health care system, which has slowed considerably during the 1980s.

In 1982, the United Kingdom imported $537 million of medical devices. The United States had the largest share of the total U.K. import market for medical devices with 28 percent, up from 25 percent in 1980 (52). It is expected that the U.S. share will continue to increase to nearly 36 percent of total imports by 1987. Increases in medical device imports from other major suppliers will reflect both increased competition among foreign suppliers to maintain their sales and decreased sales by U.K. domestic suppliers. The major new products in which U.S. suppliers are expected to do well over the next 5 years are high-technology items, such as laser technology, fiber optics, and micro-surgical equipment.

Import Requirements

The general British import regulations applicable to all imported goods do not appear to significantly impede the importation of medical devices (105). Nor are foreign manufacturers of medical devices required to obtain Government-issued clearances when their goods are imported into the United Kingdom. Foreign concerns are permitted to negotiate directly with the end-user, and there is no requirement that the transaction be reported to the Government. Imported medical devices are subject only to routine customs procedures.

As a member of the European Community, the United Kingdom does not impose tariffs on the products of European Community member states. Therefore, members can sell medical devices in the United Kingdom at a competitive advantage. The United Kingdom along with many other European countries adheres to the CCCN for the classification of medical devices. Having a standardized category of goods simplifies the import and export of medical devices.

British tariff duties do not impose a substantial barrier to the importation of medical devices. The duty rates on most medical devices range from 5 to 8 percent ad valorem and are generally comparable to or slightly below similar tariffs in the United States. Certain medical device imports, such as those intended for training and research or for sale to nonprofit institutions may be exempted altogether from the imposition of duties.

In addition to being subject to duties imposed on devices from non-European Community countries, all imported medical equipment is subject to a 15-percent value-added tax (VAT) imposed on the duty-paid value of the goods. The VAT is imposed in order to equalize the treatment of imported devices with those manufactured in the United Kingdom, which are already subject to a VAT.

Product Approval Process

Although medical devices sold in the United Kingdom are not generally subject to the drug laws or to any mandatory scheme comparable to the controls exercised by the FDA, regulations do apply to the medical device market. Many medical devices are regulated by two divisions of the Department of Health and

Social Security. The Medicines Division controls the manufacturing, licensing, clinical trial, certification, safety, efficacy, pre-market approval, labeling, quality control and adverse-reaction reporting of those devices subject to the provisions of the Medicines Act of 1968, as amended. Although the Medicines Act applies primarily to drugs, it also covers such devices as surgical sutures, dental filling substances, contact lenses, intrauterine contraceptive devices, and certain radioactive medicinal products (174).

The Supplies, Industries, and Exports Division administers the Drug Tariff, which lists products that may be prescribed and distributed through the National Health Service (NHS). In addition, this division sets specific purchasing requirements for such medical devices as X-ray equipment, hemodialysis machines, and surgical implants (174). The activities of the division are focused on devices that the Government purchases in large volume and on products that, if found to be defective, would pose a substantial hazard to the public health and welfare. Through the Supplies, Industries, and Exports Division, the Government, which is by far the largest purchaser of medical devices, routinely sets quality and safety standards for the products it purchases. These standards, adhered to by domestic procedures, must be complied with by importers in order to sell in the U.K. market.

The Government also influences, unofficially, the types and specifications of other medical devices through a voluntary system of manufacturer registration that operates through the National Health Service (174). Under the control of the Scientific and Technical Branch of the Supplies, Industries, and Exports Division, this system allows manufacturers of medical devices to voluntarily register their businesses under certain "good manufacturing practice" guides that have been developed in consultation with British trade associations.

Registration certifies that equipment manufactured by the concern meets certain safety and effectiveness criteria. The guides cover the entire manufacturing process, from training of personnel to packaging, labeling, and possible recall. The first guide, applicable to sterile, single-use medical devices, became effective in 1982. Guides are expected to be issued for numerous areas in the future.

Although NHS hospitals are not required by law to make purchases from registered manufacturers, the system contains incentives to encourage registration. The Health Service Supply Council will circulate lists of registered manufacturers along with a recommendation that products should be purchased only from listed manufacturers. In effect, then, the Scientific and Technical Branch's advisory standards will guide the purchase of medical equipment by NHS hospitals. Because these hospitals do most of the medical equipment purchasing, it will generally be good business practice for a device manufacturer to register under a "good manufacturing practice" guide, if one applies.

The combination of standards for Government purchases and reliance by private purchasers on those standards acts as an unofficial regulatory scheme for both imported and domestic medical devices sold in the United Kingdom. The result is a degree of regulation of medical devices, that, though lacking a statutory basis, is as pervasive as that existing in almost any other country. The "voluntary" registration procedure will soon augment the power of these indirect controls even further.

Certain medical devices, including electrical and radiological medical equipment, must also comply with standards issued by the British Standards Institution (BSI) (52). These standards may pose significant obstacles to U.S. manufacturers, since compliance with U.S. standards does not always satisfy all U.K. requirements. In general, compliance with the standards of BSI is now as important in the sale of electrical medical devices as compliance with a standard developed by the Supplies, Industries, and Exports Division.

Other Market Factors

Since Government agencies purchase the vast majority of all medical devices sold in the United Kingdom, marketing strategy must be aimed at Government, rather than private, procurement. Purchases by Government hospitals and other agencies have in the past been made primarily at the local level, rather than through a centralized purchasing system. This decentralized purchasing system for NHS hospitals has resulted in hospitals' buying equipment which may not be exactly what they need, or paying more for equipment because they are not buying in large quantities. In an effort to overcome these problems, NHS has recently revised its purchasing procedure to set up 17 regional purchasing centers and a new, national Supply Council to act as a central purchasing agency for high-volume equipment purchases (52).

France

The French market for all medical equipment was an estimated $356 million in 1980, with imports accounting for about 70 percent of that market (286). Exports of French medical equipment have averaged about 80 percent of imports to France. During the last decade, the United States replaced West Germany as the leading exporter of medical equipment and in 1980 provided about 24 percent of all imported medical equipment to France.

Import Requirements

In addition to the regular documents for import, numerous medical devices require technical visas, which permit surveillance of the quantity and price of imports (286). Technical visas are required for anesthetic equipment, syringes and surgical supplies, special diagnostic equipment, blood transfusion apparatus, and electrostatic units containing artificial radioactive elements.

Tariffs on most imported medical equipment range between 5 and 13 percent (286) and apply only to goods outside the European Community. Under commitments made at the Tokyo Round of GATT, these tariff rates should decrease slightly over the next few years. France does impose a VAT of 17.6 percent on most goods, including medical devices, regardless of their source.

Product Approval Process

A combination of technical standards and product approval requirements necessary for government purchases and reimbursement payments constitutes an indirect but comprehensive system of regulation. The effectiveness of this system is increased by the reliance private parties place on official standards in making their own purchasing decisions.

The French Pharmacopeia[3] sets forth detailed purity standards for drugs and "sterile devices," such as surgical dressings, sutures, certain implants, absorbent cotton, and a variety of plastic products. Pharmacopeia requirements technically apply only to products that are sold to public institutions or to products that claim to comply with the Pharmacopeia. However, their role in practice is far broader, since private purchasers also rely on compliance with Pharmacopeia requirements as an indication of quality (164).

For certain medical devices that are to be sold to public institutions, French law requires official government approval through "homologation." The Commission d'Homologation periodically lists certain categories of devices that must be approved before they can be purchased by a public institution. Manufacturers must formally apply to the commission, which requires submission of test reports by the manufacturer. At the end of the process, a proposal is made to the Ministry of Health, which issues an approval decree and a homologation number (164). Many manufacturers submit their products to the homologation process even when they are not required to do so, because products with official approval have a larger market.

Certain medical devices sold to public agencies are also subject to technical standards developed with the cooperation of industry and the Association Française du Normalization (AFNOR), a governmental standards body. These standards are imposed by various agencies of the national government (286). These products may not be imported unless the Ministère de l'Industrie, du Commerce et de l'Artisunat has certified that they conform with the applicable technical standards. If the relevant standards are developed or administered by a department other than the Ministère de l'Industrie, initial testing and approval of the device will be done by that department.

The difference between the AFNOR standards and those under the homologation process is that the AFNOR standards cover very technical matters such as the electrical workings of a device, while the homologation process is a much more general product approval process dealing with both electrical and nonelectrical devices. Compliance with AFNOR standards can be useful in marketing a product. Conformity is shown by an "NF" mark on the label, which can only be used with permission of AFNOR after testing of the product and inspection of the manufacturing premises.[4]

Other Market Factors

Government procurement is a very important factor in the French medical device market, with purchases by public hospitals accounting for the largest segment of the market. A central purchasing group representing public hospitals, the Union de Groupements d'Achats Publiques, accounts for over one-half of the medical equipment purchases by all public hospitals (376). Acceptance by this group can assure a product's success, particularly since private purchasing decisions tend to follow government procurement decisions.

Government purchases are made in one of three ways: through privately negotiated contracts, through competitive bidding, and through bidding where factors other than price are considered. But despite France's adherence to the Agreement on Government Procurement under GATT, a 1975 "Buy French" policy does apply to purchases of numerous products—including external blood collection systems, hyperbaric chambers, body scanners, and artificial kidney machines (286). The requirement for Ministry of Public Health "advice" on purchases of "innovative" equipment by the public sector (previously limited to "heavy equipment") often takes the form of approved lists of suppliers.

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[3] The French Pharmacopeia has semiofficial status in France, under the authority of the Ministry of Public Health. Although its definitions, procedures, and standards do not have the same force and effect, as for example, FDA regulations in the United States, it is used as a guideline to identify health and safety violations associated with various drugs and medical devices.

[4] See *Exporters' Encyclopedia*, at 2:481-482 (105).

In addition, an effort is being made to strengthen the capabilities of regional health authorities for providing advice on contemplated purchases. Such "advice" is unlikely to favor U.S. suppliers if viable local alternatives exist, or where a manufacturer is a significant local employer. Indeed, U.S. manufacturers have been informed that new products will not be approved by the French authorities for purchase where there is a competitive French-manufactured device (284).

France also requires companies importing diagnostic products to set up a quality control laboratory in France to recheck every shipment, regardless of whether it has undergone quality control audits in the country of origin. No shipment of medical devices will be licensed without testing in a Government-approved laboratory (444).

Federal Republic of Germany

In 1980, sales of medical equipment and supplies in the Federal Republic of Germany totaled more than $1.5 billion (188). In 1979, the United States was the leading foreign supplier of medical equipment with 25 percent of imports (377).

Import Requirements

Products of European Community, Western European, and developing countries are not subject to import duties (188). Tariff rates applicable to medical equipment from other countries average 6 to 9 percent, with a maximum of about 11 percent. Most imports are subject to a VAT of 13 percent, similar to the VAT levied on domestically manufactured products. Some imported manufactured products are subject to special excise taxes in addition to the "import equalization tax." Foreign exporters to West Germany who must pay both the tariff and the "import equalization tax" face a significant disadvantage (216).

Product Approval Process

Regulation of medical devices is similar to that existing in the United States prior to the passage of the Medical Device Amendments of 1976, with regulation of some products as an outgrowth of the regulation of pharmaceuticals. The 1976 Law on the Reform of Drug Legislation pertains to "fictitious drugs," which include devices containing a drug, devices to be introduced into the body, dressings and surgical sutures, and diagnostic products (94). Specific regulations have been promulgated to govern manufacture, licensing, clinical trials, reporting of adverse effects, and liability for damage caused by drugs.

Although fictitious drugs are not now subject to these regulations, the regulations could be extended to them in the future. Under the Drug Reform Law, the government also has a number of enforcement tools that can be used against regulated devices considered misleadingly labeled, unsafe, or ineffective.

Two provisions of the law are of special interest to importers. First, surgical suture material and certain diagnostic products may be imported outside the European Community countries only if the importer obtains certification from a competent authority of the manufacturing country (such as FDA in the United States) that the World Health Organization's good manufacturing practices have been adhered to or that the import is in the interest of the general public. West Germany is in the process of adopting its own GMP regulations for the pharmaceutical industry, and these will apply to manufacturers of fictitious drugs.

Second, the law requires any person who markets a medical device that comes under the Drug Reform Law to maintain a place of business within West Germany. The European Community recently ruled that this requirement is illegal and has asked that it be abolished, but its future is uncertain.

Although the Drug Reform Law covers a relatively small segment of the medical device industry, a much larger segment is indirectly regulated. Regulations issued under the German General Technical Law require that the manufacturer of technical medical equipment is in proper condition and that either the manufacturer or an expert has subjected the devices to final inspection (192).

Test protocols may be required from the manufacturer for certain types of equipment, and testing must be carried out at one of 34 designated institutions. Testing for most medical devices is voluntary, but is often performed because it has some commercial value for the manufacturer. However, proposals have been circulating in West Germany to make testing under this law mandatory for all electromedical devices.

Regulation of medical devices also occurs on a piecemeal basis through the work of the Deutsches Institut Für Normung (DIN), the official standards body in West Germany. DIN has developed standards in such areas as the testing, storage, labeling, and packaging of products, and the materials, dimensions, and tolerances to be used in manufacturing for a large number of medical devices. Among the medical items for which standards exist are surgical dressings, implants, and transfusion and hematological equipment. Although compliance with an applicable DIN standard is not required by law, in practice it can be a major advantage in the marketplace to have a DIN mark of approval on a product. Moreover, much interpretation of DIN standards is done in practice by West German test laboratories whose approval is very important for marketing a product in West Germany (458).

West Germany has a pharmacopeia, but with only limited applicability to medical devices. Its main focus is drugs and only a few medical devices, such as surgical sutures and dressings, are included.

Other Market Factors

West Germany is a signatory to the GATT Agreement on Government Procurement. Although government spending represents a substantial portion of all health care expenditures, purchases of medical devices are for the most part decentralized without the direct involvement of Government agencies. In practice, the chief physician in a hospital or in one of its departments makes all purchasing decisions. The major exception involves purchases of $75,000 or more by university clinics. Such purchases must be approved by the German Research Association. There is no official "Buy German" policy, but the tendency of publicly financed health care institutions is to purchase West German products.

Mexico

The market for medical equipment in Mexico is small but growing. Approximately $44.2 million was spent during 1980 on medical equipment, including medical devices (28). Imports account for nearly 85 percent of all purchases of medical equipment. The United States is the largest exporter, with 38 percent of the market in 1980. The Federal Republic of Germany (18 percent in 1980) and France (9 percent in 1980) are closest U.S. competitors. Devices for which production is labor-intensive are generally supplied domestically, while devices that require highly technological processes are often imported.

Import Requirements

The Mexican system of import control involves a dual scheme of licensing and tariffs (105). Importers may obtain a license by applying to the Ministry of Commerce. The request is considered by one of 13 committees that specialize in a particular portion of the tariff or by a special committee that considers license requests by Government agencies. Requests are usually acted on within 2 weeks. Imports by government agencies must be approved in advance by the Public Sector Imports Committee, and approval will be withheld if a domestic product is available which is reasonably competitive in price and quality.

Mexico maintains no special import requirements for most medical devices. One exception to this is that all devices to be physically connected to a patient require import permits from the Ministry of Industry and Commerce and the Ministry of Health and Assistance (378). However, these permits are neither difficult nor costly to obtain.

The majority of medical devices imported into Mexico are subject to tariffs which range from 2 to 35 percent (28). The median tariff is in the 10- to 15-percent range, somewhat higher than other countries in this study. The Mexican tariff generally follows CCCN. Mexico is not a signatory to the GATT. However, the only countries with preferential tariffs are other members of the Latin America Integration Association (Argentina, Bolivia, Brazil, Colombia, Chile, Ecuador, Paraguay, Peru, Uruguay, and Venezuela) (378).

Product Approval Process

There is no specific system of product approval for medical devices under Mexican law. Certain devices, however, require approvals from Mexican commissions that act as counterparts to U.S. utility commissions. For example, all electrical devices must be approved by the Federal Electricity Commission, a state-owned corporation, and equipment incorporating radioactive materials must receive approval from the Nuclear Energy Institute (378). There are also no official standards governing the design or use of medical equipment in Mexico. Medical products, for the most part, can be brought directly into Mexico without any preimport procedures.

Other Market Factors

The size of the Mexican medical device market and the import share of that market are limited by a number of factors. First, over 70 percent of all health care expenditures in Mexico are Government-controlled (28). The emphasis of the two major Government agencies involved in the provision of health-related services, the Institute for Social Security and the Secretariat of Health and Security, and of Mexican health care providers in general, is on the provision of basic health care services. As a consequence, there is a very limited market for sophisticated high-technology medical equipment, such as CT scanners and cardiac diagnostic equipment, in which the U.S. medical device industry is particularly strong.

Mexican governmental purchasing practices evidence a strong preference for domestically produced items. The Government will procure medical equipment from foreign manufacturers only when the equipment cannot be domestically supplied. Indeed, the Government has a "closed border" policy under which it will ban imports of products that compete directly with goods manufactured in Mexico, including those manufactured by the Mexican subsidiary of a foreign corporation. The effect of this policy on U.S. imports has not, so far, been great.

Finally, there is a highly developed system of import agents who take responsibility for obtaining licenses and negotiating with foreign suppliers. The agents arrange for the import of a good and supply the ultimate end-user. Direct sales to end-users, although not rare, are not significant in volume when compared either to sales to import agents or those made directly to the Government.

The medical devices market has also been affected by the foreign exchange difficulties that Mexico is currently experiencing. In late 1982, exchange controls were placed on all foreign remittances from Mexican banks. These controls include Government approval of import contracts requiring payment outside of Mexico, even for purchases by Government agencies.

Appendix J.—Glossary of Acronyms and Terms

Glossary of Acronyms

AAMI	— Association for the Advancement of Medical Instrumentation
AART	— American Association of Respiratory Therapists
ACRS	— Accelerated Cost Recovery System
AFNOR	— Association Francaise de Normalisation
ANSI	— American National Standards Institute, Inc.
AOA	— American Osteopathic Association
ASTM	— American Society for Testing and Materials
BMD	— Bureau of Medical Devices (Canada)
BSI	— British Standards Institution
CABG	— coronary artery bypass graft
CAPD	— continuous ambulatory peritoneal dialysis
CCCN	— Customs Cooperation Council Nomenclature
CDC	— Centers for Disease Control (PHS)
CEN	— European Committee for Standardization
CENELEC	— European Committee for Electrotechnical Standardization
CFR	— Code of Federal Regulations
CHAMPUS	— Civilian Health and Medical Program of the Uniformed Services
CID	— commercial item description
CLIA	— Clinical Laboratory Improvement Act
CLMA	— Contact Lens Manufacturers Association
CON	— Certificate of need
CPR	— customary, prevailing, and reasonable
CSA	— Canadian Standards Association
CT	— computed tomography
DEN	— Device Experience Network (FDA)
DHHS	— Department of Health and Human Services
DHSS	— Department of Health and Social Security (United Kingdom)
DIN	— Deutsches Institut für Normung
DISC	— Domestic International Sales Corp.
DME	— durable medical equipment
DOC	— Department of Commerce
DRGs	— diagnosis related groups
ERTA	— Economic Recovery Tax Act of 1981
ESRD	— end-stage renal disease
FDA	— Food and Drug Administration (PHS, DHHS)
GAO	— General Accounting Office (U.S. Congress)
GATT	— General Agreement on Tariffs and Trade
HCFA	-- Health Care Financing Administration (DHHS)
HIDI	— Health-Care Instrument and Device Institute
HIMA	— Health Industry Manufacturers' Association
HMO	— health maintenance organization
IDE	— investigational device exemption
IEC	— International Electrotechnical Commission
IFAC	— Industry Functional Advisory Committee (DOC)
IND	— investigational new drug
IV	— intravenous
IPA	— individual practice association
IPPB	— intermittent positive pressure breathing
IRS	— Internal Revenue Service
ISO	— International Organization for Standardization
ITA	— International Trade Administration (DOC)
IUD	— intrauterine device
JCAH	— Joint Commission on Accreditation of Hospitals
JIS	— Japanese Industrial Standards
MEDIPP	— Medical District Initiated Program Planning
MITI	— Ministry of International Trade and Industry (Japan)
NBS	— National Bureau of Standards (DOC)
NCCLS	— National Committee on Clinical Laboratory Standards
NCI	— National Cancer Institute (NIH)
NFPA	— National Fire Protection Association
NHLBI	— National Heart, Lung, and Blood Institute (NIH)
NHS	— National Health Service (United Kingdom)
NIADDK	— National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases (NIH)
NIH	— National Institutes of Health (PHS, DHHS)

NMR — nuclear magnetic resonance
NSF — National Science Foundation
OEA — Office of Export Administration (DOC)
OHTA — Office of Health Technology (PHS, DHHS)
OIML — International Organization for Legal Metrology
OMB — Office of Management and Budget
OTA — Office of Technology Assessment (U.S. Congress)
PHS — Public Health Service, DHHS
PMAA — premarket approval application
PRO — peer review organization
PSRO — Professional Standards Review Organization
R&D — research and development
Rehab R&D — Rehabilitation Research and Development
SBIC — Small Business Investment Corp.
SBIR — Small Business Innovation Research
SIC — Standard Industrial Classification
TEFRA — Tax Equity and Fiscal Responsibility Act of 1982
TÜV — Technischer Überwachungs Verein
UCR — usual, customary, and reasonable charges
UL — Underwriters Laboratories, Inc.
U.S.C. — United States Code
USTR — U.S. Trade Representative
VA — Veterans Administration
VAMKC — Veterans Administration Marketing Center
VAREC — Veterans Administration Rehabilitation Engineering Center
VAT — value added tax
VDE — Verband Deutscher Elektrotechniker
WHO — World Health Organization
YAG — yttrium aluminum garnet

Glossary of Terms

Applied research: Investigation whose objective is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

Basic research: Original investigation whose objective is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications in mind.

Capital costs: Expenditures for plant and equipment used in providing a service. Under Medicare's prospective hospital payment system established by the Social Security Amendments of 1983 (Public Law 98-21), hospitals' capital costs (depreciation, interest, and return on equity to for-profit institutions) are treated as passthroughs (i.e., are not subject to the new system's controls).

Certificate of need (CON): A State regulatory planning mechanism encouraged by the National Health Planning and Resources Development Act (Public Law 93-641) to control expenditures for and distribution of expensive medical care facilities and equipment. CON applications are reviewed by local health systems agencies, which recommend approval or disapproval to State health planning agencies.

Class I: One of three regulatory classes set up by the 1976 Medical Device Amendments (Public Law 94-295). Class I, general controls, contains devices for which general controls authorized by the act are sufficient to provide reasonable assurances of safety and effectiveness. Manufacturers of Class I devices must register their establishments and list their devices with the Food and Drug Administration (FDA), notify FDA before marketing a device, and conform to good manufacturing practices.

Class II: The regulatory class of devices for which general controls are considered insufficient to assure safety and effectiveness and information exists to establish performance standards.

Class III: The regulatory class of devices for which Class I general controls are insufficient to ensure safety and effectiveness, information does not exist to establish performance standards, *and* the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury.

Conditions of participation: Requirements that a provider must meet in order to be allowed to receive payments for Medicare patients. An example is the requirement that hospitals conduct utilization review.

Development: Systematic use of the knowledge or understanding gained from research in the design and development of prototypes and processes.

Device type: All products of a particular type or a grouping of separate types of devices that are similar, as categorized by FDA. FDA has classified device types according to the potential risk posed by their use and the degree of regulation required.

Diagnosis related groups (DRGs): Groupings of diagnostic categories drawn from the International Classification of Diseases and modified by the presence of a surgical procedure, patient age, presence or absence of significant comorbidities or complications, and other relevant criteria. DRGs are the case-mix measure mandated for Medicare's prospective hospital payment system by the Social Security Amendments of 1983 (Public Law 98-21).

DRG payment: The system of prospective payment for inpatient services by Medicare which was mandated by the Social Security Amendments of 1983.

Good manufacturing practices: Requirements regarding the manufacturing, packing, storage, and installation of devices required under the Medical Device Amendments of 1976 and applicable to all three regulatory classes of devices.

Investigational device exemption (IDE): A regulatory category and process under which FDA permits limited use of an unapproved medical device in controlled settings for the purpose of collecting data on safety and effectiveness. This information may subsequently be used in support of a premarketing approval application.

Medical device: Any instrument, apparatus, or similar or related article that is intended to prevent, diagnose, mitigate, or treat disease or to affect the structure or function of the body.

Medical technology: The drugs, devices, and medical and surgical procedures used in medical care, and the organizational and support systems within which such care is provided.

Nuclear magnetic resonance (NMR) imaging: A diagnostic imaging modality that uses radiowaves and powerful magnetic fields rather than ionizing radiation.

Orphan product: Defined by the Orphan Drug Act of 1983 (Public Law 97-414) as drugs and medical devices for rare diseases or conditions.

Peer review organizations (PROs): Physician organizations established by the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) to replace Professional Standards Review Organizations. Hospitals are mandated to contract with PROs to review quality of care and appropriateness of admissions and readmissions. PROs are also termed utilization and quality control peer review organizations.

Postamendments device: A medical device first marketed after May 1, 1976, when the Medical Device Amendments took effect.

Preamendments device: A medical device marketed before May 1, 1976, when the Medical Device Amendments took effect.

Premarket approval application (PMAA): An application to FDA for approval to market a new device. The sponsor of the device must submit to FDA information to document its safety and effectiveness before the drug may be marketed.

Procedure (medical or surgical): A medical technology involving any combination of drugs, devices, and provider skills and abilities. Appendectomy, for example, may involve at least drugs (for anesthesia), monitoring devices, surgical devices, and the skilled actions of physicians, nurses, and support staff.

Professional Standards Review Organizations (PSROs): Community-based, physician-directed, nonprofit agencies established under the Social Security Amendments of 1972 (Public Law 92-603) to monitor the quality and appropriateness of institutional health care provided to Medicare and Medicaid beneficiaries.

Prospective payment: Payment for medical care on the basis of rates set in advance of the time period in which they apply. The unit of payment may vary from individual medical services to broader categories, such as hospital case, episode of illness, or person (capitation).

Standard Industrial Classification (SIC) codes: A categorization of data on products and companies that is used by the U.S. Department of Commerce. Establishments (plants) are assigned to SIC "industries" on the basis of their primary line of business. However, SIC data on shipments of a specific product include all shipments of the relevant product, regardless of the "industry" in which the producing establishment is classified.

Substantially equivalent device: A device first marketed after the 1976 Medical Device Amendments that FDA has found to be similar to a device already being marketed. To be found substantially equivalent, a postamendments device need not be identical to a preamendments device, but must not differ markedly in materials, design, or energy source.

Third-party payment: Payment by a private insurer or government program to a medical provider for care given to a patient.

Transitional devices: Devices that were regulated as new drugs before enactment of the 1976 Medical Device Amendments.

References

References

1. Abelson, D. S., Director, Technical Trade Barriers, Office of the U.S. Trade Representative, Washington, DC, personal communication, Nov. 29, 1983.
2. Adams, W., Surgilite International, Inc., comments made at OTA workshop, December 1982.
3. Agress, P., "Problems Encountered in Marketing U.S. Medical Devices in Japan: Discussions Between the Two Governments Aimed at Easing Difficulties," *Food Drug Cosmetic Law J.* 38:43, 1983.
4. American Association for Respiratory Therapists, "Guidelines for the Use of Intermittent Positive Pressure Breathing," Dallas, TX, April 1979.
5. American Health Planning Association, *Report of the Commission on Capital Policy*, Washington, DC, March 1984.
6. American Hospital Association, Division of Health Financing Policy, Office of Public Policy Analysis, *Hospital-Blue Cross Contract Provisions, July 1, 1981*, AHA catalog No. 073200, Chicago, IL, February 1982.
7. American Hospital Association, *Hospital Regulation*, Report of the Special Committee on the Regulatory Process, Chicago, IL, 1977.
8. American Hospital Association, Office of Public Policy Analysis, "Incorporating Capital Costs into Medicare Prospective Prices," unpublished draft, Chicago, IL, July 1983.
9. American National Standards Institute, *Directory of International and Regional Standards Organizations* (New York: ANSI, 1982).
10. American Society for Parenteral and Enteral Nutrition, "Parenteral and Enteral Nutrition," unpublished briefing paper, Washington, DC, Nov. 18, 1982.
11. American Society for Parenteral and Enteral Nutrition, *Public and Private Insurance Coverage of Parenteral and Enteral Nutrition Services*, background paper prepared by Memel, Jacobs, Pierne & Gersh, Washington, DC, March 1983.
12. *AMP, Inc.* v. *Gardner*, 389 F. 2d 825 (1968); *cert. denied* 393 U.S. 825 (1968).
13. Anbar, M., "University-Based R&D: A New Development in National Economy," *Medical Device & Diagnostic Industry* 5(12):26-29, December 1983.
14. Anderson, G., and Ginsburg, P. B., "Prospective Capital Payments to Hospitals," *Health Affairs* 2(3):52-63, fall 1983.
15. Arakaki, E., U.S. Department of Commerce, Washington, DC, personal communications, February and August 1984.
16. Arizona Board of Regents, "Patent Policy of the Arizona Board of Regents," adopted Apr. 16, 1977.
17. Arthur D. Little, Inc., *Cost of Compliance With Good Manufacturing Practices Regulations by the Medical Device Industry*, prepared for the Food and Drug Administration, Department of Health and Human Services, contract No. 223-79-8052 (Springfield, VA: National Technical Information Service, Department of Commerce, March 1982).
18. Arthur Young & Co. and The Emergency Care Research Institute, *A Profile of the Medical Technology Industry and Governmental Policies*, final report, vol. 1, contract No. 233-79-3011, report to the National Center for Health Services Research, U.S. Department of Health and Human Services, Hyattsville, MD, June 30, 1981.
19. Axelson, P., U.S. Veterans Administration Rehabilitation Research and Development Center, Palo Alto, CA, personal communication, July 1983.
20. Ayres, S. M., "Magnitude of Use and Costs of In-Hospital Respiratory Therapy," *Am. Rev. Resp. Dis.* 122(5):11-13 (pt. 2), November 1980.
21. Baker, D. F., speech presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 10, 1982.
22. Bandy, W. C., U.S. Department of Commerce, Bureau of Industrial Economics, Washington, DC, personal communication, January 1983.
23. Banta, H. D., "Computed Tomography: Cost Containment Misdirected" (editorial), *Am. J. Public Health* 70:215, 1980.
24. Banta, H. D., Ruby, G., and Burns, A. K., "Using Coverage Policy to Contain Medicare Costs," in U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *Proceedings of the Conference on the Future of Medicare*, Committee Print No. 23 (Washington, DC: U.S. Government Printing Office, 1984).
25. Barach, A. L., and Segal, M. S., "The Indiscriminate Use of IPPB," *JAMA* 231(11):1141-1142, Mar. 17, 1975.
26. Barth, J. R., and Cordes, J. J., "Capital Markets, Government Regulation, Tax Policy and

the Financing of Medical Device Innovations," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, February 1984.

27. Barth, J. R., Cordes, J. J., and Tassey, G., "The Impact of Recent Changes in Tax Policy on Innovation and R&D," in *Strategic Management of Industrial R&D: Interdisciplinary Perspectives*, B. Bozeman, M. Crow, and A. Link (eds.) (Lexington, MA: Lexington Books/D.C. Heath & Co., 1984).
28. Batres, Valdes, Wygard y Associadoes, S. C., "Market Survey of Medical Equipment (Mexico)," prepared for U.S. Trade Center, April 1982.
29. Beck, R. H., "The Effects of Copayment on the Poor," *J. Hum. Resour.* (1):129, 1974.
30. *Becton, Dickinson & Co.* v. *Food and Drug Administration*; *United States* v. *Becton, Dickinson & Co.*; and *In the Matter of the Establishment Inspection of Bard-Parker, Division of Becton-Dickinson Co.*; 589 F. 2d 1175 (2d Cir. 1978).
31. Berenson, R., Washington, DC, personal communication, January 1984.
32. Bialys, S., U.S. Veterans Administration, Hines, IL, personal communication, May 1983.
33. Biles, B., Schramm, C. J., and Atkinson, J. G., "Hospital Cost Inflation Under State Rate-Setting Programs," *N. Engl. J. Med.* 303(12): 664, Sept. 18, 1980.
34. *Biomedical Business International,* "Medical Nutritionals: Markets, Trends, Outpatient Services and Synergies," VII(3):18-19, Feb. 8, 1984.
35. *Biomedical Business International*, "Trends in Clinical Testing," VI(14):124-126, Aug. 10, 1983.
36. Blue Cross and Blue Shield Association, "Medical Necessity Guidelines on Respiratory Care (Inpatient)," Chicago, IL, Oct. 20, 1982.
37. *The Blue Sheet*, "Health Planning Will Get Funding If Legislation Clears," 27(5):14-15, Feb. 1, 1984.
38. *The Blue Sheet*, "New York Certificate-of-Need Review to Focus on New Projects' Operating Costs," 26(25):12-13, June 22, 1983.
39. Booker, H., U.S. Veterans Administration, Washington, DC, personal communications, November 1982 and April 1984.
40. Bovbjerg, R. R., Diamond, L. H., Held, P. J., et al., "Continuous Ambulatory Peritoneal Dialysis: Preliminary Evidence in the Debate Over Efficacy and Cost," *Health Affairs* 2(2):96-102, summer 1983.
41. Bozeman, B., Crow, M., and Link, A. (eds.), *Strategic Management of Industrial R&D: Interdisciplinary Perspectives* (Lexington, MA: Lexington Books/D.C. Heath & Co., 1984).
42. Bradburd, R. M., "Veterans Administration Procurement and the Market for Medical Equipment," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, Oct. 19, 1983 (draft).
43. Braun, S. R., Smith, F. R., McCarthy, T. M., et al., "Evaluating the Changing Role of Respiratory Therapy Services at Two Hospitals," *JAMA* 245(20):2033-2037, May 22-27, 1981.
44. Brennan, M. F., "Total Parenteral Nutrition in the Cancer Patient," *New Engl. J. Med.* 305(7): 375-382, Aug. 13, 1981.
45. Breslar, J., U.S. Veterans Administration, Washington, DC, personal communications, May and June 1983.
46. Bridgman, E., "The Impact of the GATT Standards Code and United States Trade Agreement Act on Private Sector Standards Development," presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 10, 1982.
47. Britain, R., U.S. Department of Health and Human Services, Food and Drug Administration, comments made at OTA Workshop on the Medical Device Amendments of 1976, Washington, DC, May 19, 1983.
48. Britain, R., U.S. Department of Health and Human Services, Food and Drug Administration, Silver Spring, MD, personal communication, August 1983.
49. Britt, M. R., Child, S. R., and Grantham, M. L., *Reduction of Intermittent Positive Pressure Breathing (IPPB) Usage in Surgical Patients by a PSRO*, Utah PSRO, Salt Lake City, UT, n.d.
50. Brook, R. H., Williams, K. N., and Rolph, J. E., "Controlling the Use and Cost of Medical Services: The New Mexico Experimental Medical Care Review Organization—A Four-Year Case Study," *Medical Care* 16(9) (Suppl.), September 1978.
51. Bunker, J. P., Fowles, J., and Schaffarzick, R., "Evaluation of Medical Technology Strategies: Evaluation of Coverage and Reimbursement," *N. Engl. J. Med.* 306(10):620, Mar. 11, 1982.
52. Business Management Consultants, Ltd., "Survey of the United Kingdom Market for Medical Equipment," report prepared for the U.S. Department of Commerce, International Trade Administration, Office of Trade Information Services, Aldershot, Hampshire, U.K., June 15, 1983.
53. Campbell, J., "The 1976 Medical Device Amend-

ments and the 510(k) Process," presented to the Food and Drug Law Institute, Washington, DC, May 1, 1983.

54. Carney, T. P., President, Metatech Corp., paper prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.
55. Carroll, M. S., and Arnett, R. H., III, "Private Health Insurance Plans in 1977: Coverage, Enrollment, and Financial Experience," *Health Care Finan. Rev.* 1(2):3, fall 1979.
56. Carter, C., "Conditions for the Successful Use of Science," *Science* 219(4590):1295-1298, Mar. 18, 1983.
57. Chassin, M., "Chapter IV, Certificate of Need," *Medical Care* 16(10) (Suppl.):21-26, October 1978.
58. Cherniak, et al., "Home Care of Chronic Respiratory Disease," *JAMA* 208:821, 1969.
59. Chrysomilides, S. A., and Kaminski, M. V., "Home Enteral and Parenteral Nutritional Support: A Comparison," *Am. J. Clin. Nutr.* 34(10): 2271-2275, October 1981.
60. Coelen, C., and Sullivan D., "An Analysis of the Effects of Prospective Reimbursement Programs on Hospital Expenditures," *Health Care Finan. Rev.* 2(3):1, winter 1981.
61. Cohen, A. B., and Cohodes, D. R., "Certificate of Need and Low Capital-Cost Medical Technology," *Milbank Mem. Fund Q.* 60(2):307-28, spring 1982.
62. Cohen, J. S., Research Chemist, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, MD, personal communication, Aug. 1, 1983.
63. Cohodes, D. R., "The State Experience With Capital Management and Capital Expenditure Review Programs," article cited in "Health Capital Issues," papers presented at the Health Capital Conference sponsored by the Bureau of Health Facilities, Feb. 19-20, 1980.
64. Cohodes, D. R., "Which Will Survive? The $150 Billion Capital Question," *Inquiry* 20:5-11, spring 1983.
65. Collins, E., "Tax Incentives for Industrial R&D: Effects of the New Provisions and Proposals for Further Action," mimeo, National Science Foundation, Washington, DC, 1983.
66. Comanor, W. S., "Market Structure, Product Differentiation, and Industrial Research," *Q. J. Econ.* 85:639-657, November 1967.
67. Committee for Economic Development, Research and Policy Committee, *Stimulating Technological Progress* (New York: The Heffernan Press, Inc., 1980).
68. Cook, C., U.S. Veterans Administration, Washington, DC, personal communication, December 1982.
69. Coombs, F., U.S. Veterans Administration, Washington, DC, personal communication, January 1983.
70. Cordes, J. J., "The Impact of Tax and Financial Regulatory Policies on Industrial Innovation," report of a workshop sponsored by the National Research Council and the National Academy of Engineering, July 20, 1978 (Washington, DC: National Academy of Sciences, 1980).
71. Cromwell, J., Ginsburg, P., Hamilton, D., et al., *Incentives and Decisions Underlying Hospitals' Adoption and Utilization of Major Capital Equipment* (Cambridge, MA: Abt Associates, 1975), as cited in (351).
72. Cromwell, J., and Kanak, J., "The Effects of Prospective Reimbursement Programs on Hospital Adoption and Service Sharing," *Health Care Finan. Rev.* 4(2):67, December 1982.
73. Cutler, I. R., "The European Scene With Respect to Standards and National Regulatory Requirements for Medical Devices and Equipment," paper presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 9-10, 1982.
74. Cutler, S., Health Care Financing Administration, Baltimore, MD, personal communication, Aug. 17, 1983.
75. Damadian, R., Minkoff, L., Goldsmith, M., et al., "Tumor Imaging in a Live Animal by Field Focusing NMR (Fonar)," *Physiol. Chem. & Phys.* 8:61-65, 1976.
76. Damadian, R., Zaner, K., and Hor, D., "Human Tumors by NMR," *Physiol. Chem. & Phys.* 5:381-402, 1973.
77. Damadian, R., Zaner, K., Hor, D., et al., "Human Tumors Detected by Nuclear Magnetic Resonance," *Proc. Nat. Acad. Sci. USA* 71(4):1471-1473, 1974.
78. Davis, C., Health Care Financing Administration, testimony at hearing on *Proposed Prospective Reimbursement Rates for the End-Stage Renal Disease Program*, before the Subcommittee on Health, Committee on Finance, U.S. Senate, Mar. 15, 1982 (Washington, DC: U.S. Government Printing Office, 1982).
79. Demlo, L. K., Hammons, G. T., Kuder, J. M., et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Med-

ical Technologies," College of Medicine and Graduate College of University of Iowa Hospitals and Clinics, contract report prepared for the Office of Technology Assessment, U.S. Congress, October 1983 (draft).

80. *Devices and Diagnostics Letter*, "FDA Denies Petition To Simplify 510(k) Procedures," 10(33), Aug. 19, 1983.
81. *Devices and Diagnostics Letter*, "FDA Limits Number of YAG Laser Investigations," 10(50), Dec. 16, 1983.
82. *Devices and Diagnostics Letter*, "Firms Line Up Behind Petition To Revamp 510(k) Rule," 10(1), Jan. 7, 1983.
83. *Devices and Diagnostics Letter*, "HRG Takes Neuro Device Submission Argument to Dingell," 9(50), Dec. 10, 1982.
84. *Devices and Diagnostics Letter*, "Investigational Devices Need Not Be Loss-Leaders," 9(51):2, Dec. 17, 1982.
85. *Devices and Diagnostics Letter*, "Naderites Spurned On Effort To Force Device Standards," 9(49), Dec. 3, 1982.
86. *Devices and Diagnostics Letter*, "PMA Requirements May Stifle Cerebellar Stimulator," 11(2), Jan. 13, 1984.
87. *Devices and Diagnostics Letter*, "Progress Toward Revising Class II Standards Starts," 10(48), Dec. 2, 1983.
88. *Devices and Diagnostics Letter*, "YAG Laser Studies Limited to 500 Patients, 6 Months," 10(41):1, Oct. 14, 1983.
89. diMonda, R., "How Hospitals Perceive Standards," *Medical Instrumentation* 13(4):200-3, July-August 1979.
90. Dolan, A. M., "The Development of Consensus Standards for Medical Devices in Canada," *Medical Progress Through Technology* 6(3):137-40, June 1979.
91. Donaldson, J. L., Deputy Director, Office of Products Standards Policy, Office of the Director, National Bureau of Standards, Washington, DC, personal communication, Nov. 29, 1983.
92. Dowdal, T. G., U.S. General Accounting Office, letter to Carolyn K. Davis, Administrator, Health Care Financing Administration, re: Analysis of Medicare Durable Medical Equipment Claims in Georgia, Idaho, and Southern California (GAO/HRD-84-40), Feb. 13, 1984.
93. Downs, F., U.S. Veterans Administration, Washington, DC, personal communications, November 1982 and June 1983.
94. Drug Reform Law (Law on the Reform of Drug Legislation), Federal Republic of Germany, Aug. 24, 1976, Bundesgesetzblatt [BGB1].
95. Dun & Bradstreet, Dun's Financial Profiles, *1981 Industry Norms, Three Years*, vols. I and II, New York, November 1981.
96. Dunkelberg, J. S., Furst, R. W., and Roenfeldt, R. L., "State Rate Review and the Relationship Between Capital Expenditures and Operating Costs," *Inquiry* 20:240-247, fall 1983.
97. Eads, G. C., "Regulation and Technical Change: Some Largely Unexplored Influences," *Am. Econ. Rev.* 70(2):50, May 1980.
98. Eggers, P. W., Office of Research, Health Care Financing Administration, Baltimore, MD, personal communication, February 1984, as cited in (260).
98a. Eisner, R., Albert, S. H., and Sullivan, M. A., "Tax Incentives and R&D Expenditures," presented at the 16th CIRET Conference, Washington, DC, September 1983.
99. Eli Lilly & Co., "Lilly Hospital Pharmacy Survey, '82," Indianapolis, IN, 1982.
100. Emergency Care Research Institute, "NMR: Still Too Early for Answers to Many Questions," *Issues in Health Care Technology*, November 1983.
101. Engelberg, A. B., "Patent Term Extension: An Overreaching Solution to a Nonexistent Problem," *Health Affairs* 2:34-45, spring 1982.
102. EUROTASC (European Regulatory-Technical Affairs Study Committee), Six-Volume Report, September 1981.
103. Evans, C. C., U.S. Veterans Administration, Washington, DC, personal communication, Mar. 5, 1984.
104. Evans, C. C., Holden, F., and Speight, J., "A DRG Based Resource Allocation System for the Veterans Administration," Allocation Development Service, U.S. Veterans Administration, unpublished paper, 1983.
105. *Exporters' Encyclopedia*, 2:481-482, 1405-1428.
106. Farrow, S. C., Kaluzny, A. D., and Ricketts, T., "Proceedings of a Conference on Health Services Research Issues in the Veterans Administration," *J. Med. Systems* 5(1/2):1-16, 1981.
107. Feder, J., *Medicare: The Politics of Federal Hospital Insurance* (Lexington, MA: Lexington Books, 1977).
108. Feder, J., Hadley, J., and Mullner, R., "Poor People and Poor Hospitals: Implications for Public Policy," *J. Health Polit. Policy Law*, forthcoming.
109. Feil, C., Associate Manager of Public Information, Underwriters Laboratory, Northbrook, IL, personal communication, September 1983.
110. Feldstein, M. S., and Taylor, A. K., *The Rapid Rise of Hospital Costs*, a report to the President's

Council on Wage and Price Stability (Washington, DC: U.S. Government Printing Office, 1977).

111. Feldstein, P. J., "Relying on Regulation To Improve Hospital Performance," *Health Care Economics* (New York: John Wiley & Sons, 1979).

112. Fellner, W., "The Influence of Market Structure on Technological Progress," *Quality J. Econ.* 65:560, November 1951, as cited in (274).

113. Ferry, T. P., Gornick, M., Newton, M., et al., "Physicians' Charges Under Medicare: Assignment Rates and Beneficiary Liability," *Health Care Finan. Rev.* 2:49-73, winter 1980.

114. Fineberg, H. V., "Gastric Freezing—A Study of Diffusion of a Medical Innovation," in Institute of Medicine and National Research Council, *Medical Technology and the Health Care System: A Study of Equipment-Embodied Technology* (Washington, DC: National Academy of Sciences, 1979).

115. Finkel, M. J., "The Development of Orphan Products," *N. Engl. J. Med.* 307(15):963-964, Oct. 7, 1982.

116. Finkel, M. J., Director, Office of Orphan Products Development, Food and Drug Administration, Rockville, MD, personal communications, Jan. 25 and Apr. 15, 1984.

117. Flaherty, R., Director, Diagnostic Standards and Scientific Affairs, Health Industry Manufacturers Association, Washington, DC, personal communication, July 29, 1983.

118. Flink, R. C., "Standards: A Benefit or Burden to Industry?" *Medical Instrumentation* 13(4): 197-8, July-August 1979.

119. Foster, H. S., Attorney at Law, O'Conner and Hannan, Washington, DC, personal communication, April 1984.

120. Foster, H. S., "The Impact of Federal and State Regulatory Programs on the Ambulatory Laboratory Testing Industry and the Demand for Instrumentation," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, January 1984 (revised draft).

121. Foster, M. E., "Sweeping Amendments to Standards and Certification System Adopted," *East Asian Exec. Rep.* 5(7):9,13-14, July 15, 1983.

122. Fuji National City Consulting Ltd., "Survey of Japanese Markets for Medical and Dental Equipment," vol. 2, prepared for the U.S. Embassy, May 1983.

123. The Futures Group, "Characterization of Innovations Introduced on the U.S. Market in 1982," contract report prepared for the U.S. Small Business Administration, contract #SBA-6050-OA-82. Glastonbury, CT, March 1984.

124. Gellman Research Associates, Inc., *The Relationship Between Industrial Concentration, Firm Size, and Technological Innovation*, report prepared for the Office of Economic Research, Office of Advocacy, U.S. Small Business Administration, Washington, DC, May 11, 1982.

125. Giannini, M., U.S. Veterans Administration, Washington, DC, personal communication, November 1982.

126. Gibson, R. M., "National Health Expenditures, 1978," *Health Care Finan. Rev.* 1:1-36, summer 1979.

127. Gibson, R. M., and Waldo, D. R., "National Health Expenditures, 1981," *Health Care Finan. Rev.* 4(1):1-35, September 1982.

128. Gibson, R. M., Waldo, D. R., and Levit, K. R., "National Health Expenditures, 1982," *Health Care Finan. Rev.* 5(1):1-31, fall 1983.

129. Gold, J., Office of Health Planning, U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Washington, DC, personal communication, Apr. 12, 1984.

130. Goldschmidt, P. G., U.S. Veterans Administration, Washington, DC, personal communication, January 1983.

131. Grace Commission, *President's Private Sector Survey on Cost Control: Task Force Report on the Veterans Administration*, draft, Washington, DC, May 1983.

132. *Graham, et al.* v. *John Deere Co. of Kansas City, et al.*, 383 U.S. 1 (1966).

132a. Grayson, R. T., "Effects of Regulatory Controls on the Accuracy of Clinical Laboratory Tests," *J. Medical Technology* (forthcoming).

133. Greenfield, W. M., "New Approaches To Using the Determination-of-Need Process To Contain Hospital Costs," *N. Engl. J. Med.* 309(6):372-375, Aug. 11, 1983.

134. Greer, D. F., and Rhoades, S. A., "Concentration and Productivity Changes in the Long and Short Run," *South. Econ. J.* 43:1031, October 1976, as cited in (274).

135. Griessbach, L., German American Chamber of Commerce, personal communication, Nov. 29, 1983.

136. Hadley, D., Health Care Financing Adminstration, Baltimore, MD, personal communication, Aug. 11, 1983.

137. Hadley, J., "Critique of Peter Fox's 'Physician Reimbursement Under Medicare: An Overview and a Proposal for Area-Wide Physician Incentives,' " in U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *Proceedings of the Conference on the Future of Medicare*, Committee Print No. 23 (Washing-

ton, DC: U.S. Government Printing Office, 1984).

138. Hadley, J., and Feder, J., "Hospital Cost Shifting," Urban Institute working paper #3179-07 (Washington, DC: The Urban Institute, 1984).
139. Hadley, J., Holahan, J., and Scanlon, W., "Can Fee-for-Service Reimbursement Coexist With Demand Creation?" *Inquiry* 16(3):247, fall 1979.
140. Hadley, J., Juba, D., Swartz, K., et al., *Alternative Methods of Developing a Relative Value Scale of Physicians' Services* (Washington, DC: The Urban Institute, February 1983).
141. Hamilton, R., "Certificate of Need: Scope of Coverage," paper presented at the American Health Planning Association and the National Health Lawyers Association, Washington, DC, Dec. 7, 1983.
142. Harman, A. J., "Industrial Innovation and Governmental Policy: A Review and Proposal Based on Observation of the U.S. Electronics Sector," *Tech. Forecast. Soc. Change* 18:15, 1980.
143. Hayes, A. H., Jr., Statement of the Commissioner, Food and Drug Administration at Hearings on *FDA Oversight: Medical Devices*, U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, July 16, 1982, serial No. 97-144 (Washington, DC: U.S. Government Printing Office, 1982).
144. Hazelwood, C. F., Cleveland, G., Medina, D., "Relationship Between Hydration and Proton Nuclear Magnetic Resonance Relaxation Times in Tissue of Tumor-Bearing and Non-tumor Bearing Mice: Implications for Cancer Detection," *J. Natl. Cancer Inst.* 52:1849-1853, 1974.
145. Health Industry Manufacturers Association, *Guidelines for the Development of Voluntary Device Law Standards*, HIMA Report No. 79-6, Washington, DC, October 1979.
146. Health Industry Manufacturers Association, *International Activities Survey*, HIMA Document 10, vol. 2, Washington, DC, July 1980.
147. Heimburger, H. C., "Home Parenteral Nutrition," *Ala. J. Med. Sci.* 19(4):377-380, October 1982.
148. Hellinger, F. J., "The Effect of Certificate-of-Need Legislation on Hospital Investment," *Inquiry* 13:187-193, June 1976.
149. Higson, G. R., "The UK Department of Health and Social Security's Scientific and Technical Services Branch," *J. Medical Engineering and Technology* 7(3):130-35, May/June 1983.
150. Holder, J., U.S. Veterans Administration, Washington, DC, personal communication, June 1983.
151. Holland, D., "The Effect of Taxation on Effort: Some Results for Business Executives," *National Tax Association—Proceedings of the 62nd Annual Conference*, September 1969.
152. Hollis, D. P., Saryan, L. A., Eggleston, J. C., et al., "Nuclear Magnetic Resonance Studies of Cancer," *J. Natl. Cancer Inst.* 54:1469-1472, 1975.
153. *Home Health Line*, "A Big Chill Settles Over Part A Home Hyperalimentation," IX:22-24, Jan. 30, 1984.
154. *Home Health Line*, "Atlanta Home Care Seminar—National Medical Enterprises V. P. Livingston Says Home Care Low Priority for Hospitals; Manufacturers Expand Into Home Care Centers," VIII:212-214, Nov. 21, 1983.
155. *Home Health Line*, "Changing Face of Medicare Home Health" (table), VIII:28, Feb. 4, 1983.
156. *Home Health Line*, "DME Under $120 Should Be Purchased, GAO Report Says," VIII:126, July 18, 1983.
157. *Home Health Line*, "GAO Again Finds DME Excess Rental—This Time in 'High-Cost' Oxygen Concentrators," IX:53, Feb. 27, 1984.
158. *Home Health Line*, "GAO Finds Only $18 Million in HHA DME Expenditures," IX:85, Apr. 9, 1984.
159. *Home Health Line*, "Medicare Home Health Outlays Up 1,000% From 1974 (table)," VIII: 136, July 25 and Aug. 1, 1983 (combined issue).
160. *Home Health Line*, "Medicare Home Health Yearly Outlays to Break $3 Billion by End of Decade, Total Hospice Outlays Equal $815 Million Before Sunset," IX:43, Feb. 13, 1984.
161. *Home Health Line*, "NAMES Presses 'Freedom of Choice' in Hospital DME Referrals," IX:49, Feb. 20, 1984.
162. *Home Health Line*, "Region V Flattens Daily Care After Consulting HCFA; Says Patient Should Be in Skilled Nursing Facility If Cheaper," VIII:167-168, Sept. 12, 1983.
163. Howard, A. J., "European Medical Device Regulations: An Update," *Medical Device and Diagnostic Industry* 5(9):46-50, September 1983.
164. Hulse, J. W., "The Impact of Foreign Regulation on International Trade: Potential Barriers to U.S. Products," paper presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 10, 1982.
165. Iglehart, J., "Health Report/Federal Regulation of Medical Devices Gets Serious Attention in Congress," *National Journal Reports*, pp. 1184-1188, Aug. 11, 1973.
166. IMS America, Ltd., Rockville, MD, unpublished

data provided to the Office of Technology Assessment, U.S. Congress, under contract, December 1983.

167. IMS America, Ltd., *Veterans Administration Price Analysis of Hospital Supply and Pharmaceutical Products*, Order No. TE-Q1-83, Rockville, MD, May 1983.

168. Institute of Medicine and National Research Council, *Medical Technology and the Health Care System: A Study of Equipment-Embodied Technology* (Washington, DC: National Academy of Sciences, 1979).

169. International Organization for Standardization, *MEMENTO 1978 and 1983* (Geneva, Switzerland: ISO, 1978 and 1983).

170. InterStudy, "The December 1983 HMO Enrollment in the U.S.: A Mid-Year Census" (Excelsior, MN: InterStudy, 1984).

171. *In the Matter of the Establishment Inspection of Portex, Inc., Food and Drug Administration, Appellant*, 595 F. 2d 84 (1st Cir. 1979).

172. Janssen, T. J., and Saffran, G. T., "Reimbursement for Durable Medical Equipment," *Health Care Finan. Rev.* 2(3): 94, winter 1981.

173. Japan Ministry of Health and Welfare, "Measures Taken by the Japanese Ministry of Health and Welfare (MHW) for Further Opening the Japanese Market Regarding Pharmaceuticals, Food, Etc.," April 1983.

174. Jarvis, A. E., "A Detailed Review of the Medical Device Regulations of Major Importers of U.S. Products," paper presented at the Ninth Annual AAMI/FDA Conference on Medical Device Regulation, Arlington, VA, Nov. 10, 1982.

175. Jewkes, J., Sawers, D., and Stillerman, R., *The Sources of Invention*, 2d ed. (New York: Norton, 1969).

176. Joint Commission on Accreditation of Hospitals, *Accreditation Manual for Hospitals 1983*, Chicago, IL, 1982.

177. Joskow, P. L., *Controlling Hospital Costs: The Role of Government Regulation* (Cambridge, MA: The Massachusetts Institute of Technology Press, 1981).

178. Kamien, M. I., and Schwartz, N. L., "On the Degree of Rivalry for Maximum Innovative Activity," *Q. J. Econ.* 90(2):245-260, May 1976.

179. Kamien, M. I., and Schwartz, N. L., *Market Structure and Innovation* (Cambridge, MA: Cambridge University Press, 1982).

180. Kasper, J. A., *Prescribed Medicines: Use, Expenditures, and Sources of Payment*, Data Preview 9, DHHS publication No. (PHS) 82-3320, National Health Care Expenditures Study, National Center for Health Services Research, U.S. Department of Health and Human Services, Hyattsville, MD, April 1982.

181. Kaye, Scholer, Fierman, Hays, & Handler, "Governmental Barriers to International Trade in Medical Devices in the United States, United Kingdom, France, The Federal Republic of Germany, Canada, Japan, and Mexico," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, February 1984.

182. Kelly, P., and Kranzberg, M. (eds.), *Technological Innovation: A Critical Review of Current Knowledge* (San Francisco: San Francisco Press, 1978).

183. Kenney, M., independent consultant, Berkeley, CA, personal communication, Apr. 19, 1984.

184. Kessler, P., "You: Putting Teeth Into Bonding," *The Washington Post*, C5 (col. 2), July 5, 1983.

185. Ketterling, V., U.S. Department of Commerce, Bureau of Industrial Economics, Washington, DC, personal communication, February 1984.

186. Kidder, Peabody & Co., *Baxter Travenol Laboratories, Inc.: 1983 Review and Outlook, Company Follow-up*, May 13, 1983.

187. Kimberly, J. R., "Hospital Adoption of Innovations in Medical and Managerial Technology: Individual, Organizational and Contextual/Environmental Effects," Executive Summary, National Science Foundation Grant No. PRA 76-23080, March 1978.

188. Kindel, K., "Survey of the Market for Medical Equipment in Germany," prepared for the U.S. Department of Commerce, Berlin, March 1981.

189. Kleinfield, N. R., "The Home Health Care Boom," *The New York Times*, sec. D1, June 30, 1983.

190. L. W. Borgman & Co., "Financial Issues in Biotechnology," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, March 1983.

191. Lauterbur, P. C., "Image Formation by Induced Local Interactions: Examples Employing Nuclear Magnetic Resonance," *Nature* 242:190-191, 1973.

192. Law on Technical Equipment and Devices, Federal Republic of Germany, June 24, 1968, as amended Aug. 13, 1979, Bundesgesetzblatt [BGB1], p. 1432.

193. Lepon, J., and Gawron, E., Kornmeier, McCarthy, Lepon, and Harris, "Medical Device Standards and International Trade," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.

194. Lewis, P., "U.S. and Third World At Odds Over

Patents," *The New York Times*, D1 (col. 1), Oct. 5, 1982.

195. Liaison and Coordination Headquarters on Standards and Certification Systems, "Improvement of Japan's Standards and Certification Systems, Etc.," Mar. 26, 1983.
196. Liefer, L., U.S. Veterans Administration Rehabilitation Research and Development Center, Palo Alto, CA, personal communication, July 1983.
197. Louis Harris & Associates, Inc., *A Survey of Medical Device Manufacturers*, study No. 802005, report submitted to the Bureau of Medical Devices, Food and Drug Administration, U.S. Department of Health and Human Services, July 1982.
198. Luft, H. S., *Health Maintenance Organizations: Dimensions of Performance* (New York: John Wiley & Sons, Inc., 1981).
199. Lupovich, P., "Changes in the Clinical Laboratory," paper prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, February 1984.
200. Mansfield, E., *Industrial Research and Technological Innovation* (New York: W. W. Norton & Co., 1968).
201. Mansfield, E., and Wagner, S., "Organizational and Strategic Factors Associated With Probabilities of Success in Industrial R and D," *J. Business* 48:179-98, April 1975, as cited in (274).
202. Marcus, P., U.S. Department of Commerce, Washington, DC, personal communication, January 1984.
203. Markham, J. W., "Market Structure, Business Conduct, and Innovation," *Am. Econ. Rev.* 60:323, 1965, as cited in (182).
204. Martin, D. R., Director, International Investigations Staff, Executive Directorate for Regional Operations, Food and Drug Administration, Rockville, MD, personal communication, Dec. 16, 1983.
205. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "Abbott's Alpha-Fetoprotein Diagnostic Kit for Testicular Cancer," 10(8):9-10, Feb. 20, 1984.
206. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "Annual Registration of Medical Device Firms Temporarily Delayed," 10(3), Jan. 16, 1984.
207. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "Contact Lens Guidelines: FDA Is Establishing Working Group," 9(48), Nov. 28, 1983.
208. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "NMR Purchases in New York Limited to 13 Sites Under Health Planning Commission Proposal; Wisconsin, Oregon, North Carolina Also Move To Restrict Purchases," pp. 9-10, Feb. 27, 1984.
209. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), reporting on testimony of NIH Director James Wyngaarden to two subcommittees of the House Science and Technology Committee, 8(40), Oct. 4, 1982.
210. *Medical Devices, Diagnostics and Instrumentation Reports* (The Gray Sheet), "Sealants Are 'Highly Effective' and 'Safe'," 9(50):12-13, Dec. 12, 1983.
211. *Medical Device and Diagnostic Industry*, "The Effect of DRGs on Devices and Diagnostics," 6(2):31-36, February 1984.
212. *Medical World News*, "Physician-Office Lab Results Less Accurate Than Those of Licensed Labs, Study Shows," 25(3):46-47, Apr. 9, 1984.
213. Medsger, B., "The Most Captive Consumers: At the Mercy of the Wheelchair Barons," *The Progressive*, pp. 34-39, March 1979.
214. Mixon, A. M., III, President, Invacare Corp., personal communication, Aug. 16, 1983.
215. Miyamo, H., Japan Ministry of International Trade and Industry, personal communication, Nov. 16, 1983.
216. Moliter, R. M., General Electric Co., Washington, DC, personal communication, Nov. 18, 1983.
217. "More Patents Bear the Label 'Made in Japan'," *National Journal* 14:1069, June 12, 1982.
218. Morrone, F., U.S. Veterans Administration, Washington, DC, personal communication, June 1983.
219. Mosley, M., "Talking Points on U.S. Exports of Medical Instruments," paper presented at the meeting of the Association for the Advancement of Medical Instrumentation, Arlington, VA, Oct. 10, 1982.
220. Mossinghoff, G. J., Patent and Trademark Commissioner, commenting on the 1983 legislative proposals, *Chemical & Engineering News* 60(33): Aug. 16, 1982.
221. Motley, H. L., Werko, L., Cournard, A., et al., "Observations on the Clinical Use of Intermittent Positive Pressure," *J. Aviation Med.* 18:417-435, October 1947.
222. Mullin, P., Joint Commission on Accreditation of Hospitals, Chicago, IL, personal communication, Apr. 17, 1984.
223. Myers, S., and Marquis, R. G., *Successful Industrial Innovations*, NSF-No. 69-17 (Washington, DC: U.S. Government Printing Office, 1969).

224. National Academy of Sciences, *Health Care for American Veterans*, prepared for the Committee on Veterans Affairs, U.S. House of Representatives, Committee Print No. 36 (Washington, DC: U.S. Government Printing Office, 1977).

225. National Academy of Sciences, Assembly of Life Sciences, *Final Report of the Committee on Prosthetics Research in the Veterans Administration*, 1976.

226. "National Survey of Hospital and Non-Hospital Clinical Laboratories," *Laboratory Mgt.* 17(3): 33-48, March 1979.

227. Needleman, J., and Lewin, L. S., "The Impact of State Regulation on the Adoption and Diffusion of New Medical Technology," Appendix F in Institute of Medicine and National Research Council, *Medical Technology and the Health Care System: A Study of Equipment-Embodied Technology* (Washington, DC: National Academy of Sciences, 1979).

228. Nelson, R. R. (ed.), *Government and Technical Progress: A Cross-Industry Analysis* (New York: Pergamon Press, 1982).

229. Nelson, R. R., "Government Stimulus of Technological Progress: Lessons From American History," in *Government and Technical Progress: A Cross-Industry Analysis*, R. R. Nelson (ed.).

230. Nelson, R. R., "The Simple Economics of Basic Scientific Research," *J. Political Economy* 67: 297-306, June 1959.

231. Nelson, R. R., and Langlois, R N., "Industrial Innovation Policy: Lessons From American History," *Science* 219:814-818, Feb. 18, 1983.

232. Nelson, R. R., and Winter, S. G., "In Search of a Useful Theory of Innovation," *Research Policy* 6:36-76, 1977.

233. Newhouse, J. P., Manning, W. G., Morris, C. N., et al., "Some Interim Results From a Controlled Trial of Cost Sharing in Health Insurance," *N. Engl. J. Med.* 305:1501, 1981.

234. Obermayer, J., *The Role of Patents in the Commercialization of New Technology for Small Innovative Companies* (Cambridge, MA: Research & Planning Inc., 1981).

235. Olsson, J., Manager, Safety and Regulatory Engineering, General Electric Co., Medical Systems Operation, Milwaukee, WI, personal communication, Aug. 15, 1983.

236. Organization for Economic Cooperation and Development, *Innovation in Small and Medium Firms* (Paris: Organization for Economic Cooperation and Development, 1982).

237. Over, A. M., Jr., Bradburd, R. M., Williams, R. C., Jr., et al., *Determinants of Current and Future Expenditures on Durable Medical Equipment by Medicare and Its Program Beneficiaries*, contract report submitted to the Health Care Financing Administration, U.S. Department of Health and Human Services, Baltimore, MD, April 1983.

238. Palmer, F., U.S. Veterans Administration Marketing Center, Hines, IL, personal communication, May 1983.

239. Pauly, M., *Doctors and Their Workshops: Economic Models of Physician Behavior* (Chicago: University of Chicago Press, 1980).

240. Pavliscak, M., U.S. Department of Commerce, Washington, DC, personal communication, June 1984.

241. Peter Barnard Associates, "International Market Research Survey of the Canadian Market for Medical Equipment," prepared for the U.S. Department of Commerce, July 1983.

242. Pharmaceutical Affairs Law, Aug. 10, 1950, as amended.

243. Pharmaceutical Affairs Law, No. 145, 1960.

244. Pharmaceutical Manufacturers Association, *Medical Devices and Diagnostic Products Industry: A Profile*, Washington, DC: March 1982.

245. Phillips, L., National Research Director, Paralyzed Veterans of America, Washington, DC, personal communication, June 1983.

246. Pierce, A. K., "Scientific Basis of In-Hospital Respiratory Therapy," *Am. Rev. Resp. Dis.* 122(5):1-2 (pt. 2), November 1980.

247. Policy Analysis, Inc., "Evaluation of the Effects of Certificate of Need Programs," Volume III: Analytic Reports, contract report prepared for the Bureau of Health Planning and Resources Development, Health Resources Administration, Department of Health and Human Services, contract No. 231-77-0114 (Brookline, MA: Policy Analysis, Inc., August 1980.)

248. Pontoppidian, H., "Mechanical Aids to Lung Expansion in Non-intubated Surgical Patients," *Am. Rev. Resp. Dis.* 122(5): 11-13 (pt. 2), November 1980.

249. Porges, A., Assistant General Counsel, Office of the U.S. Trade Representative, personal communication, Dec. 14, 1983.

250. Powell, R. S., Program Director, Diagnostic Imaging Research Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communication, July 29, 1983.

251. *Predicasts Forecasts*, No. 91, Apr. 22, 1983.

252. Public Citizen Health Research Group, "Comments of Public Citizen Health Research Group on FDA's Proposed Classification of General and Plastic Surgery Medical Devices," Washington, DC, June 21, 1982.
253. Public Citizen Health Research Group, petition to the National Center For Devices and Radiological Health, Food and Drug Administration, to call for safety and effectiveness data on 16 devices used in obstetrics and gynecology, Washington, DC, Mar. 2, 1983.
254. Radiation Emitting Devices Act and Regulations, as amended, Nov. 8, 1977.
255. "Regulations Respecting Medical Devices," P.C. 1975-2031, Aug. 27, 1975, as amended.
256. Rettig, R. A., "End-Stage Renal Disease and the 'Cost' of Medical Technology," in *Medical Technology: The Culprit Behind Health Care Costs?* S. Altman and R. Blendon (eds.) (Washington, DC: U.S. Department of Health, Education, and Welfare, 1979).
257. Reynolds, C., U.S. Department of Health and Human Services, Food and Drug Administration, Silver Spring, MD, personal communication, February 1984.
258. Robb, W. L., Vice-President and General Manager, General Electric Co., Medical Systems Operations, Milwaukee, WI, personal communication, October 1982.
259. Roberts, E. B., et al. (eds.), *Biomedical Innovation* (Cambridge, MA: The Massachusetts Institute of Technology Press, 1981).
260. Romeo, A. A., "The Hemodialysis Equipment and Disposables Industry," contract report prepared for the Office of Technology Assessment, U.S. Congress, February 1984 (revised draft).
261. Romeo, A. A., "Interindustry and Interfirm Differences in the Rate of Diffusion of an Innovation," *Rev. Econ. Stat.* 57:311, August 1975, as cited in (274).
262. Rosenbloom, R. S., "Technological Innovation in Firms and Industries: An Assessment of the State of the Art," in *Technological Innovation: A Critical Review of Current Knowledge*, P. Kelly and M. Kranzberg (eds.) (San Francisco: San Francisco Press, 1978).
263. Rothwell, R., "Marketing a Success Factor in Industrial Innovation," *Mgt. Decision* 14(1):43, 1976.
264. Rothwell, R., "Some Indirect Impacts of Government Regulation on Industrial Innovation in the United States," *Technological Forecasting and Social Change*, Elsevier North Holland, Inc., 19:57-80, 1981.
265. Russell, L. B., "The Diffusion of Hospital Technologies: Some Econometric Evidence," *J. Human Resources* 12:482-502, fall 1977.
266. Russell, L. B., *Technology in Hospitals: Medical Advances and Their Diffusion* (Washington, DC: The Brookings Institution, 1979).
267. Safir, A., "How Ophthalmology Changed During My Career," paper prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983.
268. Sahal, D., *Patterns of Technological Innovation* (Reading, MA: Addison-Wesley, 1981).
269. Salans, L. B., Acting Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health, testimony at hearing, *The End Stage Renal Disease Program (Part 2—Treatment Standards and Methods)*, before the Subcommittee on Government Operations, House of Representatives, Apr. 28, 1982 (Washington, DC: U.S. Government Printing Office, 1982).
270. Salkever, D. S., and Bice, T. W., "The Impact of Certificate-of-Need Controls on Hospital Investment," *Milbank Mem. Fund Q.* 54(2):185-214, spring 1976.
271. Sanford C. Bernstein & Co., Inc., *The Kidney Dialysis Industry*, New York, February 1981.
272. Scheffler, R. M., and Delaney, M., "Assessing Selected Respiratory Therapy Modalities: Trends and Relative Costs in the Washington, DC Area," in *The Implications of Cost-Effectiveness Analysis of Medical Technology/Background Paper #12:Case Studies of Medical Technologies*, prepared for the Office of Technology Assessment, U.S. Congress (Washington, DC: U.S. Government Printing Office, April 1981).
273. Scherer, F. M., "Demand-Pull and Technological Invention—Schmookler Revisited," *J. Industrial Econ.* 30(3):225-237, March 1982.
274. Scherer, F. M., *Industrial Market Structure and Economic Performance*, 2d ed. (Chicago: Rand McNally College Publishing Co., 1980).
275. Schifrin, L. G., and Rich, W. J., "The Contact Lens Industry: Structure, Competition, and Public Policy," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1983 (draft).
276. Schmookler, J., *Invention and Economic Growth* (Cambridge, MA: Harvard University Press, 1966).
277. Schroeder, S., and Showstack, J. A., "Financial Incentives to Perform Medical Procedures and Laboratory Tests: Illustrative Models of Office Practice," *Medical Care* 16(4):289-298, April 1978.
278. Schwartz, S., American College of Physicians,

Philadelphia, PA, personal communication, July 18, 1983.

279. Scitovsky, A. A., and McCall, N., "Coinsurance and the Demand for Physician Services Four Years Later," *Soc. Sec. Bull.* 40:19, May 1977.

280. Shapley, W. H., Teich, A. H., and Weinberg, J. P., *AAAS Report VIII: Research and Development, FY 1984*, a report prepared for the Executive Officer and the AAAS Committee on Science, Engineering, and Public Policy (Washington, DC: American Association for the Advancement of Science, 1983).

281. Shepard, D. S., Associate Professor, Harvard School of Public Health, Center for the Analysis of Health Practices, Boston, MA, personal communication, Apr. 30, 1984.

282. Shepard, D. S., and Karon, S. L., *The Market for Wheelchairs: Innovations and Federal Policy*, contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1984 (forthcoming).

283. Shils, M. E., "Registry of Patients on HPN," in *Home Parenteral Nutrition* (symposium proceedings, American Society for Parenteral and Enteral Nutrition), pp. 42-44, Washington, DC, 1980.

284. Sholer, J., Abbott Laboratories, Chicago, IL, personal communication, Oct. 6, 1983.

285. Showstack, J. A., Blumberg, B. D., Schwartz, J., et al., "Fee-for-Service Physician Payment: Analysis of Current Methods and Their Development," *Inquiry* 16(3):230, fall 1979.

286. Sira Institute Ltd., "Report on Medical Equipment Study—France," vol. 2, prepared for the U.S. Embassy, Kent, England, Mar. 31, 1981.

287. Skalnik, B., "IPPB: A Question of Quality," *Resp. Ther.* 6:81-83, November-December 1976.

288. Sommer, J., Deputy Director, The American Legion, Washington, DC, personal communication, July 1983.

289. Stanford University, "Policy on Tangible Research Property," memo from the Vice Provost and Dean of Graduate Studies and Research to members of the Academic Council and members of the Academic Staff-Research, Mar. 16, 1982.

290. Steiger, E., The Cleveland Clinic, Cleveland, OH, personal communication, April 1984.

291. Steinberg, E. P., and Cohen, A. B., "Nuclear Magnetic Resonance Imaging Technology: A Clinical, Industrial and Policy Analysis," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1984.

292. Stevenson, G. L., "FEC Acceptance, Growth, Cost Benefits Confirmed," *Emergence*, June 1983 (special issue).

293. Stewardson, J. D., Regulatory Standards Administrator, Cobe Laboratories, Inc., Lakewood, CO, personal communications, Dec. 6 and 13, 1983.

294. *Sugarman* v. *Forbragd*, 405 F. 2d 1189 (9th Cir. 1968).

295. Swartz, K., Senior Analyst, The Urban Institute, Washington, DC, personal communication, April 1984.

295a. Swartz, K., The Urban Institute, "The Changing Face of the Uninsured," paper prepared for presentation at the First Annual Meeting of the Association for Health Services Researchers, Panel on "Health Care for the Poor in an Era of Retrenchment," Washington, DC, June 11, 1984.

296. Swartz, K., "Who Has Been Without Health Insurance? Changes Between 1963 and 1979," Urban Institute working paper (Washington, DC: The Urban Institute, April 1984).

297. Swift, C., National Cancer Institute, Bethesda, MD, personal communication, Apr. 12, 1984.

298. Thompson, F., *Health Policy and the Bureaucracy: Politics and Implementation* (Cambridge, MA: The Massachusetts Institute of Technology Press, 1983).

299. Traub, J., National Institute for Handicapped Research, Washington, DC, personal communication, February 1984.

300. Travers, P., U.S. Congress, General Accounting Office, Washington, DC, personal communication, April 1984.

301. Turner, R., Mexico Desk Officer, Office of Trade Administration, U.S. Department of Commerce, Washington, DC, personal communication, Aug. 30, 1983.

302. *United States* v. *An Article of Drug . . . Bacto-unidisk*, 394 U.S. 784 (1969).

303. U.S., *Federal Register* 41:22620, June 4, 1976.

304. U.S., *Federal Register* 44:53577, Sept. 14, 1979.

305. U.S., *Federal Register* 45:65619, Oct. 3, 1980.

306. U.S., *Federal Register* 45:69678, Oct. 21, 1980.

307. U.S., *Federal Register* 45:76183, Nov. 18, 1980.

308. U.S., *Federal Register* 45:81769, Dec. 12, 1980.

309. U.S., *Federal Register* 46:57568-69, Nov. 24, 1981.

310. U.S., *Federal Register* 47(189):42906, Sept. 29, 1982.

311. U.S., *Federal Register* 47:2810, Jan. 19, 1982.

312. U.S., *Federal Register* 47:24332, June 3, 1982 (Initiation of Investigation pursuant to 19 U.S.C. §337).

313. U.S., *Federal Register* 47:53402, Nov. 26, 1982.

314. U.S., *Federal Register* 47:54990, Dec. 7, 1982.
315. U.S., *Federal Register* 48(2):299-315, Jan. 4, 1983.
316. U.S., *Federal Register* 48(92), Mar. 11, 1983, Final Rule, Department of Health and Human Services, Health Care Financing Administration, 42 CFR, Part 405.
317. U.S., *Federal Register* 48:13020, Mar. 29, 1983.
318. U.S., *Federal Register* 48:24014, May 27, 1983.
319. U.S., *Federal Register* 48:25126, June 3, 1983.
320. U.S., *Federal Register* 48:27723, June 17, 1983.
321. U.S., *Federal Register* 48:40272, Sept. 6, 1983.
322. U.S., *Federal Register* 48:40960, Sept. 12, 1983 (Institution of Investigation pursuant to 19 U.S.C. §337).
323. U.S., *Federal Register* 48:56778, Dec. 23, 1983.
324. U.S., *Federal Register* 49:1177, Jan. 10, 1984.
325. U.S. Congress, Congressional Budget Office, *The Effect of PSROs on Health Care Costs: Current Findings and Future Evaluations* (Washington, DC: U.S. Government Printing Office, June 1979).
326. U.S. Congress, Congressional Budget Office, *The Impact of PSROs on Health Care Costs: Update of CBO's 1979 Evaluation* (Washington, DC: U.S. Government Printing Office, January 1981).
327. U.S. Congress, Congressional Budget Office, *Veterans Administration Health Care: Planning for 1990*, Washington, DC, February 1983.
328. U.S. Congress, Congressional Research Service, *Medical Devices: A Brief Review of Legislation and Issues Related to Regulation* (Washington, DC: U.S. Government Printing Office, 1974).
329. U.S. Congress, General Accounting Office, "Centers for Disease Control Should Discontinue Certain Diagnostic Tests and Charge for Others," report No. 83-37, Washington, DC, Apr. 16, 1983.
330. U.S. Congress, General Accounting Office, *Computed Tomographic Scanners: Opportunity for Coordinated Federal Planning Before Substantial Acquisitions*, Report No. HRD-78-41, Washington, DC, January 1978.
331. U.S. Congress, General Accounting Office, *Federal Regulation of Medical Devices—Problems Still To Be Overcome*, GAO/HRD-83-53 (Gaithersburg, MD: General Accounting Office, September 1983).
332. U.S. Congress, General Accounting Office, Human Resources Division, "VA Needs To Improve Its Quality Assurance Program for Medical Supply and Equipment Items" (PLRD-82-44) unpublished memorandum report, Washington, DC, February 1982.
333. U.S. Congress, General Accounting Office, *Medicare Payments for Durable Medical Equipment Are Higher Than Necessary*, Comptroller General's Report to the Congress, GAO/HRD-82-61, Washington, DC, July 1982.
334. U.S. Congress, General Accounting Office, *Problems With Evaluating the Cost Effectiveness of Professional Standards Review Organization* (Washington, DC: U.S. Government Printing Office, July 19, 1979).
335. U.S. Congress, General Accounting Office, *VA Needs Better Visibility Over Medical Center Purchases*, report No. PSAD 81-16, Washington, DC, December 1980.
336. U.S. Congress, House Committee on Energy and Commerce, *FDA Oversight: Medical Devices*, hearings before the Subcommittee on Oversight and Investigations, July 16, 1982, serial No. 97-144 (Washington, DC: U.S. Government Printing Office, 1982).
338. U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health and the Environment, "Oversight Hearing on the Medical Device Amendments of 1976," Washington, DC, Feb. 24, 1984.
338. U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Medical Device Regulation: The FDA's Neglected Child*, An Oversight Report on FDA Implementation of the Medical Device Amendments of 1976, Committee Print 98-F (Washington, DC: U.S. U.S. Government Printing Office, May 1983).
339. U.S. Congress, House Committee on Interstate and Foreign Commerce, *Medical Devices*, hearings before the Subcommittee on Public Health and the Environment, Oct. 23-24, 1973, serial No. 93-61 (Washington, DC: U.S. Government Printing Office, 1973).
340. U.S. Congress, House of Representatives, *The Medical Device Amendments of 1976*, 94th Cong., 2d sess., 1976, House Report No. 94-853 (Washington, DC: U.S. Government Printing Office, 1976).
341. U.S. Congress, Office of Technology Assessment, *Diagnosis Related Groups (DRGs) and Medicare Program: Implications for Medical Technology—A Technical Memorandum*, GPO stock No. 052-003-00919-6 (Washington, DC: U.S. Government Printing Office, July 1983).
342. U.S. Congress, Office of Technology Assess-

ment, *The Impact of Randomized Clinical Trials on Health Policy and Medical Practice—Background Paper*, GPO stock No. 052-003-00924-2 (Washington, DC: U.S. Government Printing Office, 1983).

343. U.S. Congress, Office of Technology Assessment, *The Implications of Cost-Effectiveness Analysis of Medical Technology*, GPO stock No. 052-003-00765-7 (Washington, DC: U.S. Government Printing Office, August 1980).

344. U.S. Congress, Office of Technology Assessment, *Medical Devices and the Veterans Administration—A Technical Memorandum*, Washington, DC, in press, n.d.

345. U.S. Congress, Office of Technology Assessment, *Medical Technology and Costs of the Medicare Program*, GPO stock No. 052-003-00957-9 (Washington, DC: U.S. Government Printing Office, July 1984).

346. U.S. Congress, Office of Technology Assessment, *Medical Technology Under Proposals To Increase Competition in Health Care*, GPO stock No. 052-003-00892-1 (Washington, DC: U.S. Government Printing Office, 1982).

347. U.S. Congress, Office of Technology Assessment, *Patents and the Commercialization of New Technology* (Washington, DC: U.S. Government Printing Office, 1984 (in press)).

348. U.S. Congress, Office of Technology Assessment, *Policy Implications of the Computed Tomography (CT) Scanner*, GPO stock No. 052-003-00565-4, (Washington, DC: U.S. Government Printing Office, August 1978).

349. U.S. Congress, Office of Technology Assessment, *Policy Implications of the Computed Tomography (CT) Scanner: An Update*, GPO stock No. 052-003-00793-2 (Washington, DC: U.S. Government Printing Office, January 1981).

350. U.S. Congress, Office of Technology Assessment, *The Safety, Efficacy, and Cost Effectiveness of Therapeutic Apheresis*, GPO stock No. 003-052-00918-8 (Washington, DC: U.S. Government Printing Office, 1983).

351. U.S. Congress, Office of Technology Assessment, *Strategies for Medical Technology Assessment*, GPO stock No. 052-003-00887-4 (Washington, DC: U.S. Government Printing Office, 1982).

352. U.S. Congress, Office of Technology Assessment, *Technology and Handicapped People*, GPO stock No. 052-003-00874-2 (Washington, DC: U.S. Government Printing Office, 1982).

353. U.S. Congress, Office of Technology Assessment, *Technology, Innovation, and Regional Economic Development: Census of State Government Initiatives for High-Technology Industrial Development—Background Paper*, GPO stock No. 052-003-00912-9 (Washington, DC: U.S. Government Printing Office, May 1983).

354. U.S. Congress, Office of Technology Assessment, *Technology, Innovation, and Regional Economic Development: Encouraging High-Technology Development—Background Paper #2*, GPO stock No. 052-003-00942-1 (Washington, DC: U.S. Government Printing Office, February 1984).

355. U.S. Congress, Senate, *Clinical Laboratory Improvement Act of 1977*, S. Report No. 95-360, 95th Cong., 1st sess. (Washington, DC: U.S. Government Printing Office, 1977).

356. U.S. Congress, Senate Committee on Finance, *End-Stage Renal Disease (ESRD) Program Under Medicare*, Committee Print 97-9, September 1981 (Washington, DC: U.S. Government Printing Office, 1982).

357. U.S. Constitution, Article 1, Section 8, Clause 8 (the patent clause of the Constitution).

358. U.S. Council of Economic Advisers, *Economic Report of the President and the Annual Report of the Council of Economic Advisers* (Washington, DC: U.S. Government Printing Office, February 1983).

359. U.S. Department of Agriculture, Department of Commerce, Department of State, and Office of the U.S. Trade Representative, *Report to the United States Congress on the Agreement on Technical Barriers to Trade—"Standards Code"* (Washington, DC: U.S. Government Printing Office, 1983).

360. U.S. Department of Commerce, Bureau of the Census, *1963 Census of Manufactures*, Industry Series, MC63-I-36E and MC63-I-38A (Washington, DC: U.S. Government Printing Office, 1966).

361. U.S. Department of Commerce, Bureau of the Census, *1972 Census of Manufactures*, Industry Series, MC72-I-36E and MC72-I-38B (Washington, DC: U.S. Government Printing Office, 1976).

362. U.S. Department of Commerce, Bureau of the Census, *1977 Census of Manufactures*, Industry Series, MC77-I-38B and MC77-I-36F (Washington, DC: U.S. Government Printing Office, June 1980).

363. U.S. Department of Commerce, Bureau of the Census, *1977 Census of Manufactures*, General Summary, Subject Series, MC77-SR-1 (Washington, DC: U.S. Government Printing Office, April 1981).

364. U.S. Department of Commerce, Bureau of the Census, *1982 Census of Manufactures*, Preliminary Report Industry Series, MC82-I-36F-3(P), MC82-I-38B-1(P), MC82-I-38B-2(P), MC82-I-38B-3(P), MC82-I-38B-4(P) (Washington, DC: U.S. Government Printing Office, 1984).
365. U.S. Department of Commerce, Bureau of the Census, *1979 Annual Survey of Manufactures*, Value of Product Shipments, M79(AS)-2 (Washington, DC: U.S. Government Printing Office, October 1981).
366. U.S. Department of Commerce, Bureau of the Census, *Annual Survey of Manufactures*, Statistics for Industry Groups and Industries, for years 1958, 1963, 1972, 1977 and 1981.
367. U.S. Department of Commerce, Bureau of the Census, *Statistical Abstract of the United States: 1982-83* (103d ed.) Washington, DC, 1982.
368. U.S. Department of Commerce, Bureau of Industrial Economics, *1983 U.S. Industrial Outlook* (Washington, DC: U.S. Government Printing Office, January 1983).
369. U.S. Department of Commerce, Bureau of Industrial Economics, *1984 U.S. Industrial Outlook* (Washington, DC: U.S. Government Printing Office, January 1984).
370. U.S. Department of Commerce, Bureau of Industrial Economics, Capital, Energy, and Productivity Studies Division, Washington, DC, unpublished data, January 1984.
371. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Producer Goods, Science and Electronics Division, "United States Exports of Selected Commodities by Country, January-December 1981," unpublished, Washington, DC, Mar. 5, 1982.
372. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Producer Goods, Science and Electronics Division, "United States Exports of Selected Commodities by Country, January-September 1982," unpublished, Washington, DC, Nov. 23, 1982.
373. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Producer Goods, Science and Electronics Division, "United States Imports of Selected Commodities by Country, January-December 1981," unpublished, Washington, DC, Mar. 5, 1982.
374. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Producer Goods, Science and Electronics Division, "United States Imports of Selected Commodities by Country, January-September 1982," unpublished, Washington, DC, Nov. 26, 1982.
375. U.S. Department of Commerce, Bureau of Industrial Economics, Office of Research, Analysis, and Statistics, Washington, DC, unpublished data, 1984.
376. U.S. Department of Commerce, International Trade Administration, *Country Market Survey: Medical Equipment France*, CMS 78-010, Washington, DC, June 1978.
377. U.S. Department of Commerce, International Trade Administration, *Country Market Survey: Medical Equipment Germany*, CMS 82-516, Washington, DC, February 1982.
378. U.S. Department of Commerce, International Trade Administration, *Country Market Survey: Medical Equipment Mexico*, CMS 79-004, Washington, DC, February 1979.
379. U.S. Department of Commerce, International Trade Administration, *Technical Barriers to Trade*, vol. 4 (Washington, DC: U.S. Government Printing Office, 1981).
380. U.S. Department of Commerce, International Trade Administration, *The Tokyo Round Trade Agreements Technical Barriers to Trade*, vol. 4 (Washington, DC: U.S. Government Printing Office, September 1981).
381. U.S. Department of Commerce, Patent and Trademark Office, Office of Patent Program and Documentation Control, unpublished data, Washington, DC, February 1984.
382. U.S. Department of Commerce, Patent and Trademark Office, Office of Technology Assessment and Forecast, "OTAF Custom Report, All Technologies Report, January 1963-June 1983" (mimeo), Washington, DC, 1983.
383. U.S. Department of Commerce, Patent and Trademark Office, Washington, DC, unpublished data, 1984.
384. U.S. Department of Health and Human Services, Food and Drug Administration, *FDA Compliance Policy Guide No. 7155g.03*, Silver Spring, MD, Oct. 1, 1980.
385. U.S. Department of Health and Human Services, Food and Drug Administration, unpublished data, Silver Spring, MD, 1983.
386. U.S. Department of Health and Human Services, *Bureau of Medical Devices Standards Survey 1982, International Edition* (Washington, DC: U.S. Government Printing Office, 1982).
387. U.S. Department of Health and Human Services, Food and Drug Administration, Bureau of Medical Devices, "Policy for Class II Medical Devices," unpublished internal draft, Silver Spring, MD, August 1982.
388. U.S. Department of Health and Human Serv-

ices, Food and Drug Administration, Bureau of Medical Devices, *Product Development Protocol Guideline,* Silver Spring, MD, 1980.

389. U.S. Department of Health and Human Services, Food and Drug Administration, Bureau of Medical Devices, *Regulatory Requirements for Marketing a Device* (Washington, DC: U.S. Government Printing Office, 1982).

390. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, compilation of unpublished data from the U.S. Patent and Trademark Office, Washington, DC, December 1983.

391. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, *Baseline Data on the Availability of Medical Devices and In-Vitro Diagnostic Products,* OPE Study 54 (Rockville, MD: Food and Drug Administration, Office of Planning and Evaluation, July 1980).

392. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, *Baseline Data On Medical Device Establishments,* OPE Study 59 (Rockville, MD: Food and Drug Administration, Office of Planning and Evaluation, September 1981).

393. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, *Baseline Data on Medical Device Industries in the Census of Manufactures,* OPE Study 53 (Rockville, MD: Food and Drug Administration, Office of Planning and Evaluation, July 1980).

394. U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, Rockville, MD, unpublished data, 1983.

395. U.S. Department of Health and Human Services, Health Care Financing Administration, *1979 PSRO Program Evaluation* (Washington, DC: U.S. Government Printing Office, 1980).

396. U.S. Department of Health and Human Services, Health Care Financing Administration, *1981 End-Stage Renal Disease Annual Report to Congress* (Washington, DC: U.S. Government Printing Office, 1981.)

397. U.S. Department of Health and Human Services, Health Care Financing Administration, "Annual Report to the Congress from the Secretary of Health and Human Services on the Professional Standards Review Organizations Program Fiscal Year 1980," mimeo, February 1981.

398. U.S. Department of Health and Human Services, Health Care Financing Administration, "Draft Report of HCFA Task Force on Independent Laboratories," Aug. 17, 1983, as cited in Foster, 1984.

399. U.S. Department of Health and Human Services, Health Care Financing Administration, Office of Research and Demonstrations, *Medicare: Use of Home Health Services, 1980,* prepared by Kathryn D. Barrett, Baltimore, MD, July 1983 (draft).

400. U.S. Department of Health and Human Services, Health Care Financing Administration, "PSRO Evaluation," *Health Care Financing: Research and Demonstrations in Health Care Financing 1980-1981,* HCFA publication No. 03144, Rockville, MD, 1982.

401. U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, unpublished data supplied by G. Wilson, Bethesda, MD, December 1983.

402. U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute, *Task Force Report on Pulmonary Technology,* NIH publication No. 81-2110, Bethesda, MD, July 1981.

403. U.S. Department of Health and Human Services, National Institutes of Health, National Institute for Neurological and Communicable Disease and Stroke, Request for Proposals, "Orphan Products Development Studies" (RFP #NIH-NINCDS-8407), Bethesda, MD, Jan. 23, 1984.

404. U.S. Department of Health and Human Services, National Institutes of Health, Office of Program Planning and Evaluation and the Division of Research Grants, *NIH Data Book 1983,* Washington, DC, June 1983.

405. U.S. Department of Health and Human Services, Public Health Service, *Annual Report: Activities of the Orphan Products Board,* March 1982-May 1983, Washington, DC, 1983.

406. U.S. Department of Health and Human Services, Public Health Service, Bureau of Health Maintenance Organizations and Resources Development, Office of Health Planning, *Status Report on State Certificate of Need Programs,* Rockville, MD, March 1983.

407. U.S. Department of Health and Human Services, Request for Proposal No. HCFA-84-015, *Operation of Utilization and Quality Control Peer Review Organizations,* Feb. 28, 1984.

408. U.S. Department of Health and Human Services, unpublished statistical data, 1983.

409. U.S. Department of Health, Education, and

Welfare, Health Care Financing Administration, Professional Standards Review Organization 1978 Program Evaluation, HEW publication No. HCFA-03000, Washington, DC, January 1979.

410. U.S. Department of Health, Education, and Welfare, National Institutes of Health, *Antenatal Diagnosis*, NIH publication No. 79-1973, Bethesda, MD, April 1979.

411. U.S. Department of Health, Education, and Welfare, Public Health Service, *PSRO: An Initial Evaluation of the Professional Standards Review Organization*, "Vol. 1: Executive Summary," Washington, DC, February 1978.

412. U.S. Department of Health, Education and Welfare, et al., *Rehabilitation Engineering: A Plan for Continued Progress* (Charlottesville, VA: Rehabilitation Engineering Center, University of Virginia, 1978).

413. U.S. Department of Health, Education, and Welfare, Public Health Service, *Report of the President's Biomedical Research Panel*, "Appendix A: The Place of Biomedical Science in Medicine and the State of Science," DHEW publication No. (0S) 76-501, Washington, DC, Apr. 30, 1976.

414. U.S. Department of the Treasury, Internal Revenue Service, *A General Description of the Corporation Sourcebook*, publication 647 (Washington, DC, U.S. Government Printing Office, revised June 1983).

415. U.S. Department of the Treasury, Internal Revenue Service, *Corporation Income Tax Returns*, Statistics of Income, for years 1963, 1967, 1972, 1977 and 1980, Washington, DC, U.S. Government Printing Office.

416. U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1963, 1967, 1977, and 1980, Washington, DC, U.S. Government Printing Office.

417. U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1976-80, as cited in (26).

418. U.S. Department of the Treasury, Office of Tax Analysis, unpublished data, Washington, DC, 1983.

419. U.S. Executive Office of the President, Office of the U.S. Trade Representative, *A Preface to Trade* (Washington, DC: U.S. Government Printing Office, 1982).

420. U.S. Executive Office of the President, Office of the U.S. Trade Representative, "Status of Tokyo Round MTN Agreement Signatures and Acceptances," Nov. 1, 1983.

421. U.S. National Science Foundation, *Federal Funds for Research and Development: Fiscal Years 1980, 1981, and 1982*, NSF 81-325 (Washington, DC: NSF, 1981).

422. U.S. National Science Foundation, *National Patterns of Science and Technology Resources, 1982*, NSF 82-319, Washington, DC, 1982.

423. U.S. National Science Foundation, *Research and Development in Industry, 1979*, detailed statistical tables, NSF 81-324, Washington, DC, 1981.

424. U.S. National Science Foundation, "Survey of Industrial Research and Development," conducted by the U.S. Bureau of the Census, Washington, DC, 1982.

425. U.S. Small Business Administration, *The State of Small Business: A Report to the President* (Washington, DC: U.S. Government Printing Office, 1984).

426. U.S. Veterans Administration, *1982 Annual Report*, Washington, DC, 1983.

427. U.S. Veterans Administration, Assistant Inspector General for Auditing, "Report of Audit: Procurement and Monitoring of Pacemakers," Project No. 101A-79-42, Washington, DC, Feb. 13, 1980.

428. U.S. Veterans Administration, *Brief of Office of Procurement and Supply*, unpublished, Washington, DC, December 1982.

429. U.S. Veterans Administration, Department of Medicine and Surgery, "Chief Medical Director's Preface to Strategic Outlook," draft 5, version 2, Washington, DC, May 1983.

430. U.S. Veterans Administration, Department of Medicine and Surgery, letter to Honorable Alan K. Simpson, Chairman, Senate Committee on Veterans Affairs, concerning the VA Rehabilitation Engineering Center (VAREC), Washington, DC, May 12, 1983.

431. U.S. Veterans Administration, Department of Medicine and Surgery, *Veterans Administration Prosthetic and Sensory Aids Program Since World War II* (Washington, DC: U.S. Government Printing Office, 1977).

432. U.S. Veterans Administration, *Medical District Initiated Program Planning: Guidance for the Preparation of Medical District Plans*, vol. 1, Washington, DC, June 1983.

433. U.S. Veterans Administration, Office of Planning and Program Evaluation, *Rehabilitative Engineering Research and Development Program Evaluation*, Washington, DC, August 1981.

434. U.S. Veterans Administration, Office Of Procurement and Supply, "Evaluation of New Products," Washington, DC, January 1983.

435. U.S. Veterans Administration, Rehabilitation

Research and Development Service, "Development and Evaluation Program," Washington, DC, 1983.

436. Urban Systems Research and Engineering, and Policy Analysis, Inc., *Certificate of Need Programs: A Review, Analysis, and Annotated Bibliography of the Research Literature*, prepared under contract No. HRA-231-77-0114 for the Department of Health, Education, and Welfare, publication No. (HRA) 79-14006 (Washington, DC: U.S. Government Printing Office, November 1978).
437. Utterback, J. M., "Innovation in Industry and the Diffusion of Technology," *Science* 183:620-626, Feb. 15, 1974.
438. Utterback, J. M., and Abernathy, W. J., "A Dynamic Model of Process and Product Innovation," *Omega* 3:639-656, 1975, as cited in (259).
439. "VA Prosthetics . . . Some Recommendations," *DAV Magazine* 24(8):8-9, August 1982.
440. Venture Capital Journal, "Capital Transfusion 1982," 23(1):6, January 1983.
441. Venture Capital Journal, "Evolution of an Industry: Venture Capital Redefined for the 1980's," January 1980.
442. Venture Capital Journal, "Venture Capital Disbursements 1981: A Statistical Overview," 22 (6):7, June 1982.
443. Venture Economics, Wellesley Hills, MA, "Venture Capital Investment in the Medical Health Care Field," contract report prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, August 1983.
444. Vlassembrouck, J. M., Surgical Products Division, 3M, Minneapolis, MN, personal communication, Dec. 21, 1983.
445. Von Hippel, E., "Appropriability of Innovation Benefit as a Predictor of Functional Locus of Innovation," unpublished, MIT Sloan School of Management, Cambridge, MA, 1979, as cited in (259).
446. Von Hippel, E., "A Review of Data Bearing on the User's Role in Industrial Innovation," unpublished, MIT Sloan School of Management, Cambridge, MA, 1978, as cited in (259).
447. Wagner, J., "The Economic Evaluation of Medicine: A Review of the Literature," prepared for the Pharmaceutical Manufacturers of America, mimeo, Oct. 1, 1982.
448. Wagner, J. L., et al., *Final Report: A Study of the Impact of Reimbursement Strategies on the Diffusion of Medical Technologies*, Vol. II: Appendices, report submitted to the Health Care Financing Administration, HCFA/HHS grant # 18-P-97113/3-01 (Washington, DC: The Urban Institute, 1982).
449. Wagner, L., Program Analyst, Office of the Director, National Institutes of Health, Bethesda, MD, personal communication, Dec. 30, 1983.
450. Warner, K. E., "Effects of Hospital Cost Containment on the Development and Use of Medical Technology," *Milbank Mem. Fund Q.* 56(2):187-211, 1978.
451. *Washington Report on Medicine and Health* 37(39):4, Oct. 3, 1983.
452. *Washington Report on Medicine and Health* 38(9):1, Feb. 27, 1984.
453. *Washington Report on Medicine and Health*, "Perspectives: Health Planning Looks to the Future," 37(48), Dec. 5, 1983.
454. Weinstein, M. C., and Stason, W. B., "Cost-Effectiveness of Coronary Artery Bypass Surgery," *Circulation* 66(5) Part II, AHA Monograph No. 92, *Technology Assessment Forum on Coronary Artery Bypass Surgery: Economic, Ethical and Social Issues*, November 1982.
455. Westphal, M., Frazier, E., and Miller, M. C., "Changes in Average Length of Stay and Average Charges Generated Following Institution of PSRO Review," *Health Services Research* 14(4): 253-265, winter 1979.
456. Williams, K., Health Insurance Association of America, Washington, DC, personal communication, December 1982.
457. Willingmyre, G. T., *Reuse of Single-Use Hemodialyzers* (Washington, DC: Health Industry Manufacturers Association, 1979).
458. Willingmyre, G. T., Vice President for Technical Affairs, Health Industry Manufacturers Association, comments made at meeting, Nov. 28, 1983.
459. Wilson, et al., "Intermittent Positive Pressure Breathing," *Calif. Med.* 87:161, 1957.
460. Wilson, G. H., Special Assistant for Diagnostic Imaging Research, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communications, June 24, 1983 and September 1983.
461. Wineman, R., memorandum to file, re summary of meeting concerning end-stage renal disease issue, Jan. 21, 1980, reprinted in *The End Stage Renal Disease Program (Part 2-Treatment Standards and Methods,* Hearing before Subcommittee of the Committee on Government Operations, House of Representatives, Apr. 28, 1980 (Washington, DC: U.S. Government Printing Office, 1982).
462. Wisconsin Hospital Association, *Report on*

WHA's Evaluation of the Wisconsin Certificate of Need Program, July 23, 1982 (working draft).

463. Wishinsky, H., Vice President, Scientific and Regulatory Affairs, Professional Products Group, Miles Laboratories, Inc., Elkhart, IN, personal communication, Dec. 14, 1983.

464. Witt, A., U.S. Department of Health and Human Services, Food and Drug Administration, Office of General Counsel, Food and Drug Division, personal communication, April 1984.

465. Wright, D., U.S. Veterans Administration, Rehabilitation Engineering Center, New York, NY, personal communication, June 1983.

466. Zakupowsky, A., and Sunley, E., "An Early Assessment of the Capital Cost Recovery System for R&D Equipment Provided by the Economic Recovery Tax Act of 1981," working paper prepared for the National Science Foundation, Washington, DC, September 1982.

467. Ziment, I., "Intermittent Positive Pressure Breathing," *Respiratory Care,* G. Burton, G. Gee, and J. Hodgkin (eds.) (Philadelphia: J. B. Lippincott, 1977).

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